

UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS

NEW ENGLAND CARPENTERS HEALTH  
BENEFITS FUND, PIRELLI ARMSTRONG  
RETIREE MEDICAL BENEFITS TRUST,  
TEAMSTERS HEALTH & WELFARE FUND  
OF PHILADELPHIA AND VICINITY,  
PHILADELPHIA FEDERATION OF  
TEACHERS HEALTH AND WELFARE FUND,  
DISTRICT COUNCIL 37, AFSCME - HEALTH  
& SECURITY PLAN; JUNE SWAN;  
MAUREEN COWIE and BERNARD GORTER,

Plaintiffs,

v.

FIRST DATABANK, INC., a Missouri  
corporation, and McKESSON CORPORATION,  
a Delaware corporation,

Defendants.

Civil Action: 1:05-CV-11148-PBS

Judge Patti B. Saris

[FILED UNDER SEAL]

**DECLARATION OF LORI A. SCHECHTER IN SUPPORT OF MCKESSON  
CORPORATION'S MEMORANDUM IN OPPOSITION TO CLASS  
CERTIFICATION  
[REDACTED VERSION]**

I, Lori A. Schechter, declare as follows:

1. I am a partner in the law firm of Morrison & Foerster and one of the attorneys of record for McKesson Corporation ("McKesson") in this action. I submit this declaration in support of McKesson's memorandum in opposition to class certification.

2. True and correct copies of documents and deposition transcript excerpts produced to McKesson in this action are attached as exhibits to this declaration as follows:

<b>Tab</b>	<b>Producing Party or Witness Affiliation</b>	<b>Description</b>
<b>1</b>	<b>Aetna (TPP)</b>	
1A		FILED UNDER SEAL
<b>2</b>	<b>Dr. Ernst Berndt</b>	
2A		Report of Independent Expert Professor Ernst R. Berndt to Judge Patti B. Saris, dated February 9, 2005, submitted in <i>Pharm. III</i> (excerpts only)
<b>3</b>	<b>Blue Cross Blue Shield Montana (TPP)</b>	
3A		Deposition of Tina Wong, dated September 28, 2004, taken in <i>Pharm. III</i>
<b>4</b>	<b>Caremark (PBM)</b>	
4A		Declaration of Gregory Madsen of Caremark, dated December 18, 2006
4B		FILED UNDER SEAL
4C		FILED UNDER SEAL
4D		FILED UNDER SEAL
4E		FILED UNDER SEAL
4F		FILED UNDER SEAL
4G		FILED UNDER SEAL
4H		FILED UNDER SEAL
4I		FILED UNDER SEAL
4J		FILED UNDER SEAL
4K		FILED UNDER SEAL
4L		FILED UNDER SEAL
4M		FILED UNDER SEAL
<b>5</b>	<b>District Council 37 (Named Plaintiff)</b>	
5A		FILED UNDER SEAL
5B		FILED UNDER SEAL



<b>Tab</b>	<b>Producing Party or Witness Affiliation</b>	<b>Description</b>
5C		FILED UNDER SEAL
5D		FILED UNDER SEAL
5E		FILED UNDER SEAL
5F		FILED UNDER SEAL
5G		FILED UNDER SEAL
5H		FILED UNDER SEAL
5I		FILED UNDER SEAL
5J		FILED UNDER SEAL
5K		FILED UNDER SEAL
5L		FILED UNDER SEAL
<b>6</b>	<b>Express Scripts, Inc. (PBM)</b>	
6A		Declaration of Edward Ignaczak, dated January 23, 2007
6B		Declaration of Christina F. Macinski, dated January 24, 2007 [ATTACHMENTS FILED UNDER SEAL]
6C		FILED UNDER SEAL)
6D		FILED UNDER SEAL
6E		FILED UNDER SEAL
6F		FILED UNDER SEAL
6G		FILED UNDER SEAL
6H		FILED UNDER SEAL
6I		FILED UNDER SEAL
6J		FILED UNDER SEAL
6K		FILED UNDER SEAL
6L		FILED UNDER SEAL
6M		FILED UNDER SEAL
6N		FILED UNDER SEAL
6O		FILED UNDER SEAL
6P		FILED UNDER SEAL
6Q		FILED UNDER SEAL
6R		FILED UNDER SEAL
6S		FILED UNDER SEAL
6T		FILED UNDER SEAL
6U		FILED UNDER SEAL
6V		Express Scripts 2002 Drug Trend Report (ESI-277-00012343-12509)
6W		Express Scripts 2003 Drug Trend Report (ESI-277-000012511-12606)
<b>7</b>	<b>First DataBank</b>	

<b>Tab</b>	<b>Producing Party or Witness Affiliation</b>	<b>Description</b>
	<b>(Defendant)</b>	
7A		Deposition of Kay Morgan of First DataBank, dated January 12, 2005, taken in <i>Pharm. III</i>
<b>8</b>	<b>Dr. Hartman (Plaintiffs' Expert)</b>	
8A		Deposition of Raymond S. Hartman, dated October 4, 2006 and October 5, 2006
<b>9</b>	<b>Harvard Pilgrim (TPP)</b>	
9A		FILED UNDER SEAL
<b>10</b>	<b>Susan Hayes (Plaintiffs' Expert)</b>	
10A		FILED UNDER SEAL
<b>11</b>	<b>Health Care Cost Containment Corporation (TPP)</b>	
11A		FILED UNDER SEAL
<b>12</b>	<b>Humana (TPP)</b>	
12A		FILED UNDER SEAL
12B		FILED UNDER SEAL
<b>13</b>	<b>John Deere Health Plans (TPP)</b>	
13A		Deposition of Carol Sidwell of John Deere Health Care, Inc., dated September 17, 2004, taken in <i>Pharm. III</i>
<b>14</b>	<b>KPMG (Claims Auditor)</b>	
14A		FILED UNDER SEAL
<b>15</b>	<b>Medco (PBM)</b>	
15A		FILED UNDER SEAL
15B		FILED UNDER SEAL
15C		FILED UNDER SEAL
15D		FILED UNDER SEAL
15E		FILED UNDER SEAL

<b>Tab</b>	<b>Producing Party or Witness Affiliation</b>	<b>Description</b>
15F		FILED UNDER SEAL
<b>16</b>	<b>New England Carpenters Health Benefits Fund (Named Plaintiff)</b>	
16A		Deposition of James W. Buckley, Jr. of New England Carpenters, dated October 20, 2006
16B		Contract between New England Carpenters and AdvancePCS effective April 1, 2001 (CARP 00026-58)
16C		Integrated Prescription Drug Program Master Agreement between Medco Health Solutions, Inc. and the National Labor Alliance of Health Care Coalitions, Inc., entered into as of July 1, 2005 and Member Fund Addendum (CARP 00059-90)
16D		New England Carpenters Health Benefits Plan Book (2005) (CARP 00091-00189)
<b>17</b>	<b>PBMI Report (Industry Publication)</b>	
17A		The Prescription Drug Benefit Cost and Plan Design Survey Report, Pharmacy Benefit Management Institute, Inc. (PBMI) (2004)
17B		The Prescription Drug Benefit Cost and Plan Design Survey Report, Pharmacy Benefit Management Institute, Inc. (PBMI) (2006)
<b>18</b>	<b>Philadelphia Federation of Teachers Health and Welfare Fund (Named Plaintiff)</b>	
18A		FILED UNDER SEAL
18B		FILED UNDER SEAL
<b>19</b>	<b>Pirelli Armstrong Retiree Medical Benefits</b>	

<b>Tab</b>	<b>Producing Party or Witness Affiliation</b>	<b>Description</b>
	<b>Trust (Named Plaintiff)</b>	
19A		FILED UNDER SEAL
19B		FILED UNDER SEAL
19C		FILED UNDER SEAL
19D		FILED UNDER SEAL
19E		FILED UNDER SEAL
<b>20</b>	<b>Segal (Benefit Consultant)</b>	
20A		FILED UNDER SEAL
<b>21</b>	<b>SelectHealth (TPP)</b>	
21A		Deposition of Eric Cannon of SelectHealth, dated October 11, 2006
21B		FILED UNDER SEAL
<b>22</b>	<b>Teamsters Health and Welfare Fund of Philadelphia and Vicinity (Named Plaintiff)</b>	
22A		FILED UNDER SEAL
22B		FILED UNDER SEAL
22C		Summary Plan Description of the Plan Benefits of the Teamsters Health and Welfare Fund, January 2001 (THWF0001-34)
22D		Summary of Benefits Schedule, Teamsters Health & Welfare Fund of Philadelphia and Vicinity, July 1, 2000 (THWF 0147-152)
22E		Teamsters Health & Welfare and Pension Funds online summary of benefits coverage effective January 1, 2003 (THWF 0181-83)
22F		Letter from Joel Goodman of General Prescription Programs, Inc. to William Einhorn dated November 14, 2003 enclosing Prescription Drug Services Provider Agreement between Teamsters and GPP (THWF 1849-1863)
22G		FILED UNDER SEAL

I declare under penalty of perjury under the laws of the United States that the foregoing is true and correct.

Executed this 24th day of January, 2007, in San Francisco, California.

By:

/s/ Lori A. Schechter  
Lori A. Schechter

**CERTIFICATE OF SERVICE**

I hereby certify that a true copy of the above document was served upon each other party via overnight mail on January 24, 2007.

/s/ Lori A. Schechter  
Lori A. Schechter

# **Exhibit 2A**

FEBRUARY 9, 2005

132. While prescription volume dispensed through mail order was relatively low, and variable within the sample of PBMs, the trend towards utilization of this channel of distribution was already clearly increasing.<sup>184</sup>

**B. 2. Implications of Diverse Ownership for Preserving “Secret” Information**

133. An important implication of the patterns of diversified ownership and heterogeneous scale and scope of operations among PBMs is that commercial information regarding common negotiable contractual terms, such as rebates, discounts, audit rights, fee structures, penalties, risk assignment and other services offered is widely dispersed. This makes it difficult for any important information to remain uncovered on a sustained basis.

134. Commercial information concerning PBMs contracting and operations is known not only directly by those clients who contract with PBMs, but also by the diverse PBM owners – sometimes independent, but also commonly insurers, managed care organizations, retailers and wholesalers, as well as by the numerous health benefit consultant firms (e.g., Mercer, Segal, Towers Perrin, Wyatt, Hewitt Associates) who assist these various entities. While confidentiality commitments may make the terms of a specific contract “secret”, general knowledge concerning what is negotiable and what is the range of terms typically offered is widespread. The presence of these various entities, each familiar with various aspects of PBM operations and finances, acts as a market discipline on the individual PBMs, even the larger ones.<sup>185</sup>

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<sup>184</sup> HCFA Master Contract [1996] *supra*, pp. 31-38.

<sup>185</sup> A 2003 Goldman Sachs industry analyst’s report notes that consolidation among the Blue Cross – Blue Shield franchises not only has resulted in the Blues’ captive PBM replacing a previously outsourced independent PBM (citing Anthem’s acquisition of Trigot, which will be serviced beginning in 2004 by Anthem’s internal PBM, a contract loss for Medco), but that managed care’s internal PBMs are now also competing aggressively to provide PBM service to outside unaffiliated entities (citing PacifiCare Health Systems). See Goldman Sachs Global Equity Research, *Healthcare: Supply Chain -- Pharmacy Benefit Managers, United States*, October 16, 2003, pp. 12-13.



Expert Dr. Raymond S. Hartman concludes that competition among PBMs is insufficient, citing as support the physician-administered Lupron scandal:

“The analyses put forward by Defendants’ experts, particularly Dr. Gaier, are flawed and insufficient to demonstrate that existing PBM competition, specifically, and provider competition, generally, were sufficient to eliminate the AWP scheme. If such competition exists, it should have been sufficient to dissipate and eliminate the significant payor injury and economic damages found and pled guilty to in the Lupron matter. It was not.”<sup>274</sup>

This is a massive case, and in dealing with it the distinction between self-administered and physician-administered drugs is necessary and useful.

**A. Self-Administered Drugs**

205. Both sides in this matter agree that in the context of self-administered drugs, PBMs play a central role; I have documented those views earlier in this report. Plaintiffs allege that competition among PBMs is not effective.<sup>275</sup> The Federal Trade Commission appears to disagree. While competition among PBMs may not conform to the undergraduate microeconomics textbook example of a perfectly competitive market (in which all buyers are either fully or at least equally informed, and everyone is a price taker), federal regulatory authorities have concluded that PBM competition is “vigorous”.

206. Specifically, over the years the PBM industry has been closely monitored by the FTC (in both the Clinton and subsequent Bush administrations), and in some cases when it concluded competition might be harmed, it used its regulatory powers to intervene (e.g., to require firewalls between drug manufacturers and the PBMs they owned). As late as last year, in the context of investigating possible anticompetitive effects of horizontal consolidation among

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<sup>274</sup> *Rebuttal Declaration of Dr. Raymond S. Hartman in Support of Plaintiff’s Motion for Class Certification*, December 16, 2004, pp. 19-20.

<sup>275</sup> See, for example, *Rebuttal Declaration of Dr. Raymond S. Hartman in Support of Plaintiff’s Motion for Class Certification*, December 16, 2004, pp. 19-20, 72-82.

two of the largest PBMs -- the Caremark/ AdvancePCS acquisition -- the FTC allowed the transaction to go forward, stating:

“We concluded that these large employers are not likely to encounter anticompetitive effects from the acquisition in light of the competition that will exist following this transaction. Competition from the remaining independent, full-service PBMs with national scope – Medco, Express Scripts, and the merged Caremark/Advance PCS {Footnote 3 Not Reproduced} – and significant additional competition from several health plans and several retail pharmacy chains offering PBM services should suffice to prevent this acquisition from giving rise to a potentially anticompetitive price increase...”<sup>276</sup>

“At most, the acquisition is likely to increase the bargaining power of the merged PBM and to increase its shares (and correspondingly reduce the pharmacies’ shares) of the gains flowing from contracts between the PBM and the pharmacies. It is likely that some of the PBM’s increased shares would be passed through to PBM clients {Footnote 6 Here Reproduced Next}. We anticipate that competition among PBMs will remain vigorous in the wake of the Caremark/AdvancePCS acquisition, and that this competition is likely to cause PBMs to pass on at least some of their cost savings to their customers in order to gain or retain their business.”<sup>277</sup>

In the context of self-administered drugs, therefore, Plaintiffs’ arguments and conclusions appear to be at variance with those of the FTC, and my own analysis discussed earlier in this report. If competition among PBMs is vigorous, even if the self-administered AWPIDs were artificially inflated, injury and damages to third party payors do not follow, particularly on a class-wide basis. Since lack of competition among PBMs is crucial to Plaintiff’s theory, this would appear to undermine their allegations, and certainly their assumption of class-wide injury and damages. Plaintiffs have not, in my judgment, addressed this issue effectively.

207. In support of their claim that competition among PBMs is not sufficient, Plaintiffs point to the facts that even as the “spread” between AWP and ASP facing retail and mail order

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<sup>276</sup> Statement of the Federal Trade Commission, *In the Matter of Caremark Rx, Inc./Advance PCS*, File No. 031 0239, p. 2. Available online at [www.ftc.gov/os/caselist/0310239/040211ftcstatement0310239.pdf](http://www.ftc.gov/os/caselist/0310239/040211ftcstatement0310239.pdf), last accessed 1/16/05.

<sup>277</sup> Statement of the Federal Trade Commission, *In the Matter of Caremark Rx, Inc./Advance PCS*, File No. 031 0239, p. 3. Available online at [www.ftc.gov/os/caselist/0310239/040211ftcstatement0310239.pdf](http://www.ftc.gov/os/caselist/0310239/040211ftcstatement0310239.pdf), last accessed 1/16/05.

pharmacies for generic drugs has increased over time, the average reimbursement rates for generic self-administered drugs paid by third party payors to retailers have not fallen commensurately, implying that pharmacies have benefited and that PBMs have not been able to provide a competitive market discipline on these generic drug transactions.<sup>278</sup> Plaintiffs' empirical argument that retail (and PBM mail order) "spreads" for generic self-administered drugs have grown more rapidly than have reductions in reimbursements paid by third party payors to retailers is credible. But even if true, this does not necessarily imply a lack of effective competition among PBMs.

208. As I pointed out earlier in this report, generic drug costs are typically only 10-20% of third party payor total prescription drug costs, and third party payors are understandably gratified whenever they achieve a generic for brand substitution switch. Once having achieved a cost saving from the substantial price difference between a brand and its bioequivalent generic, the third party payor (and or its PBM) understands that the additional, incremental savings it might obtain from negotiating lower generic prices with retailers are likely to be relatively small. However, even when relatively small, those incremental cost savings are present, and perhaps it is that possibility that the FTC referred to in the second paragraph of the above FTC quote when it envisaged possible increased buying power for PBMs resulting from the Caremark/AdvancePCS acquisition. The FTC footnote quoted above also suggests the FTC expected part of the lower prices obtained by PBMs in their dealings with retailers would be passed on to third party payors and their beneficiaries.

209. In summary, the Plaintiffs' theory in the context of self-administered drugs requires that competition among PBMs be insufficient to prevent injury and damages to third

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<sup>278</sup> See, for example, *Declaration of Raymond S. Hartman In Support of Plaintiffs' Motion for Class Certification*, September 3, 2004, p. 13.

party payors. In my judgment Plaintiffs have not put forward a convincing argument supporting the notion that competition among PBMs is inadequate. Plaintiffs' contention is also at variance with conclusions reached by the FTC.<sup>279</sup>

210. There is one other matter that merits attention in this context. Even if Plaintiffs argument concerning lack of competition among PBMs were true, to the extent they owned and operated their own PBMs (and recall that the ownership structure of the PBMs has been and continues to be very diverse), third party payors would seem to me to have benefited from the allegedly fraudulent AWP scheme, and thus they would appear to face conflicts as members of the proposed class. I will not comment on this further.

211. Issues of typicality, commonality and variability are frequently at the crux of deliberations involving class certification. Before addressing some of those issues, however, I first summarize my understanding of the methodology that Plaintiff's Expert Dr. Raymond Hartman proposes to employ in assessing class-wide liability and damages.

212. In assessing whether the proposed end-payer classes were damaged, Plaintiffs' Expert Dr. Hartman proposes first to compute the spreads between AWP and ASP "for drugs unaffected by the scheme and fraud", and then use these as "yardsticks" in comparison with spreads observed "for the drugs subject to this litigation". In cases where he determines the latter spreads are larger than the former, Dr. Hartman proposes to employ his yardsticks along with mathematical and algebraic formulae "to determine the spread that would have been used

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<sup>279</sup> This is not to say that PBMs are currently exempt from litigation and government investigations. See, for example, "The United States Settles Its Anti-Fraud Claims for Injunctive Relief and 20 State Attorneys General Settle Unfair Trade Practices Claims Against Medco Health Solutions: Medco to Provide Price Information to Doctors and Patients and Pay \$29 Million Plus To States in Damages, Fees, and Restitution – Federal Damages Case Continues", U. S. Department of Justice press release, April 26, 2004, available online at [www.usdoj.gov/usao/pae/News/Pr/2004/apr/medcoinjunctivereliefrelease.pdf](http://www.usdoj.gov/usao/pae/News/Pr/2004/apr/medcoinjunctivereliefrelease.pdf), last accessed 12/31/2004.

**Attachment A**



**CURRICULUM VITAE**

*Ernst R. Berndt*  
*Louis B. Seley Professor of Applied Economics*  
*Alfred P. Sloan School of Management*  
*Massachusetts Institute of Technology*

*Director, National Bureau of Economic Research,*  
*Program on Technological Progress and Productivity Measurement*

15 August 2004

**PERSONAL DATA**

M.I.T. Address	Home Address	Other Address
Massachusetts Institute of Technology A.P.Sloan School of Management 50 Memorial Dr., E52-452 Cambridge, MA 02142 (617) 253-2665 Fax (617)258-6855	43 Peacock Farm Road Lexington, MA 02421 (781) 862-2084 Fax (781) 862-1905	National Bureau of Economic Research 1050 Massachusetts Ave., Cambridge, MA 02139 (617) 588-1420 Fax (617) 868-2742
Place and Date of Birth	Citizenship	E-mail Address
Crespo, Entre Rios, Argentina 13 April 1946	U.S. Citizen	<a href="mailto:eberndt@mit.edu">eberndt@mit.edu</a> <a href="mailto:berndt@rcn.com">berndt@rcn.com</a>

**Education and Degrees:**

B.A. (Honors) - 1968  
Department of Economics  
Valparaiso University  
Valparaiso, Indiana 46383

M.S. (1971) and Ph. D. (1972)  
Department of Economics  
The University of Wisconsin  
Madison. Wisconsin 53706

Major Field - Public Finance  
Minor Fields - Demography,  
Econometrics

D. Phil., Honorary (1991)  
Uppsala University  
Uppsala, Sweden

**Ph.D. Thesis Title:**

"The Economic Theory of Separability,  
Substitution and Aggregation with an  
Application to U.S. Manufacturing,  
1929-1968"

**Thesis Committee:**

Laurits R. Christiansen, Chair  
Arthur S. Goldberger  
Charles E. Metcalf

**Academic Awards:**

Christ College Scholar, Valparaiso  
University (1965-1968)

National Science Foundation Trainee  
(1969-1970)

National Science Foundation Fellow  
(1970-1971 and 1971-1972)

Most Cited Economist Under Age 40  
in 1985

Journal of Economic Perspectives  
Vol. 3, No.4, Fall 1989, p. 143, and  
The Journal of Economic Education  
Vol. 20, No.4 Fall 1989, p. 413.

**Academic Awards (continued):**

Elected Fellow, The Econometric Society, 1994

Distinguished Alumnus Award,  
Valparaiso University, March 31, 1996

Excellence Award in Mental Health Policy and Economics Research, International Center of Mental Health Policy and Economics, Venice, Italy, March 2003 for article published in the March 2002 issue of The Journal of Mental Health Policy and Economics (see item #123 in publications listed below)

Listed in Who's Who in America

**Current Positions:**

Professor of Applied Economics, MIT  
July 1, 1980 - present

Awarded Louis B. Seley Chaired  
Professorship, February 1997

Director, National Bureau of  
Economic Research, Program on  
Productivity and Technological Change,  
2000 – present

Adjunct Professor of Applied Economics,  
Harvard Medical School, Division of Health  
Care Policy and Research, 2001 - present

**Previous Positions Held:**

Research Economist  
Office of Emergency Preparedness  
Executive Office of the President  
U.S. Government  
Washington, D.C.  
September 1971 - December 1972

Assistant Professor  
Department of Economics  
University of British Columbia  
January 1973 - June 1976

Associate Professor  
Department of Economics  
University of British Columbia  
June 1976 - June 1980

**Previous Positions Held  
(Continued):**

Visiting Scholar  
Department of Economics  
Massachusetts Institute of Technology  
July 1977 - June 1978

Visiting Scholar  
Department of Economics  
Stanford University  
January - August 1985

Visiting Scholar  
Harvard Business School  
July 1990 - June 1991

Area Head, Economics, Finance and  
Accounting, MIT Sloan School,  
July 1992 through June 1995

Visiting Professor of Applied Economics  
Harvard Medical School, Division of  
Health Care Policy and Research  
July 1996- June 1997

**Other Professional Activities:**

Elected Member and Member,  
Executive Committee  
Conference on Income and Wealth  
National Bureau of Economic Research  
1978 - present

Panel Resource Group Member  
U.S. National Academy of Sciences  
National Research Council  
Committee on Nuclear and Alternative  
Energy Systems (CONAES)  
March 1976 - May 1978

Associate Editor of the Book Review  
Section, Journal of The American  
Statistical Association



1977 - 1981

Editorial Advisory Board

Resources and Energy

1979 - present

Member, Board of Editors

Energy Journal

1979 - 1988

**Other Professional Activities  
(Continued):**

Associate Editor

Journal of Business Administration

1982 - present

Program Co-Chairman

Second Annual Meeting of the

International Association of Energy

Economists

Churchill College, Cambridge University

Cambridge, England, June 22-24 1980

Research Associate

National Bureau of Economic Research

Productivity and Technical Change

Program, and Health Care Program

1980 - present

Conference Co-Organizer (with Zvi

Griliches), NBER Workshop on

Measurement Issues, Investment, and

Productivity

Summer 1983, 1984, 1986 - 1999; with

others, 2000 - present

Associate Editor

Journal of Econometrics

April 1985 - February 1991

Associate Editor

Land Economics

April 1985 - February 1991

Member, Editorial Board

Journal of Economics and Management

**Other Professional Activities  
(Continued):**

Strategy

February 1991 - December 1998

Member, Editorial Board

Economic Inquiry

September 1991 - present

Member

Dean's Advisory Council

College of Business Administration

Valparaiso University

Valparaiso, Indiana

September 1985 - present

Conference Co-Organizer (with William  
Barnett and Halbert White)

Third Austin Symposium in Economics

University of Texas at Austin

May 22-23, 1986

Conference Co-Organizer (with  
W. Erwin Diewert and Jack Triplett)

Jubilee Anniversary of the NBER

Conference on Research in Income  
and Wealth

Washington, D.C., May 12-13, 1988

Editor

Journal of Productivity Analysis

1987 - 1991

Member, Special Advisory Panel

National Science Foundation

Science and Technology Centers, 1988

Conference Co-Organizer (with Timothy  
Bresnahan, Zvi Griliches, and Marilyn  
Manser), NBER Conference on Output  
Measurement in the Service Sectors,  
Charleston, South Carolina,  
May 3-5 1990

Conference Co-Organizer (with Peter  
Englund, Bengt-Christer Ysander and

Lennart Hjarmalsson), Productivity  
Growth in the Service Sectors, Uppsala,  
Sweden, May 22-24, 1991

Member, Advisory Panel  
National Science Foundation  
Measurement Methods and Data  
Improvement Programs, 1990

**Other Professional Activities  
(Continued):**

Economic Consultant and Academic  
Affiliate  
Analysis Group, Inc.  
Cambridge, MA, 1985 - present

Member, Advisory Committee on  
Service Statistics, Statistics Canada  
Ottawa, Canada  
December 1991 -- February 2000

Member  
Christ College, Alumni Advisory Board  
Valparaiso University, Valparaiso, IN  
January 1992 - present

Member, Committee of Visitors,  
Program in Economics, National Science  
Foundation  
July 1992

Member, Research Consortium,  
Financial Executives Research  
Foundation, 1992 - 1995

Member, Editorial Board  
Southern Economic Journal  
July 1993 - present

Conference Co-Organizer (with Thomas  
W. Malone and Laurence C. Rosenberg)  
"The Productivity Impacts of Information  
Technology Investments," Charleston,  
South Carolina, November 11-13, 1993

Member, External Review Committee,  
Pennsylvania State University,  
Department of Economics,  
March-April, 1994

Appointed Representative of the  
American Economic Association to the  
U.S. Census Bureau Advisory Committee  
1996 – 2000; co-chairman, 1999 - 2000

Member and Chair, National Bureau of  
Economic Research, Human Subjects  
Investigation Review Board, 1998 - present

Member, National Academy of Sciences  
Panel on the Conceptual, Measurement and  
Other Statistical Issues in Developing Cost-  
of-Living Indexes, 1999 - 2001

Member and Chair, Federal Economic  
Statistics Advisory Committee, 2000 –  
present

Member, American Economic Association,  
Committee on Economic Statistics, 2002 –  
present

Panel Review Member, National Science  
Foundation, Program on Methodology,  
Measurement and Statistics, Spring 2003 –  
present.

Intermittent Detail to the U.S. Food and  
Drug Administration, Office of the  
Commissioner, 5600 Fishers Lane,  
Rockville, MD 20857, October 1, 2003 –  
June 30, 2004.

Editorial Board, RAND Forum for Health  
Economics and Health Policy, March 2004  
– present

Co-Director, MIT Biomedical Enterprise  
Program, July 2004 - present

*Publications (in chronological order)*

**ARTICLES/CHAPTERS/REPORTS:**

1. Berndt, Ernst R. and Laurits R. Christensen, "The Internal Structure of Functional Relationships: Separability, Substitution, and Aggregation," Review of Economic Studies, Vol. XL (3), July 1973, pp. 403-410.
2. Berndt, Ernst R. and Laurits R. Christensen, "The Translog Function and the Substitution of Equipment, Structures, and Labor in U.S. Manufacturing, 1929-68," Journal of Econometrics, Vol. 1 (1), 1973, pp. 81-114.
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33. Berndt, Ernst R., William Crown, Stan Finkelstein, Joel Kallich, Haim Erder, Stacey Long and Gary Lyman, “The Impact of Anemia and its Treatment on Employee Disability and Medical Costs,” revised December 2003. Under review, Pharmacoeconomics.
34. Berndt, Ernst R., Joel Kallich, Anne McDermott, Xiao Xu, M. Haim Erder, Howard Lee and John Glaspy, “Reductions in Anemia and Fatigue are Associated with Improvements in Productivity,” revised manuscript, December 2003. Under review, Value in Health.
35. White, Alan G., Jaison R. Abel, Ernst R. Berndt and Cory W. Monroe, “Hedonic Price Indexes for Personal Computer Operating Systems and Productivity Suites,” Cambridge, MA: NBER Working Paper No. 10427, April 2004.
36. Berndt, Ernst R., Adrian H. B. Gottschalk and Matthew W. Strobeck, “Critical Issues in Re-Engineering the Drug Development Process: Results from a Survey of Industry and the FDA,” MIT Sloan School unpublished manuscript, August 2004.

**Attachment B**

**OIG Reports Related to Medicare & Medicaid**

<b><u>Date</u></b>	<b><u>Report Title</u></b>	<b><u>Key Findings / Recommendations</u></b>
Nov. 1992	"Physicians' Costs for Chemotherapy Drugs" (A-02-91-01049)	For a small, judgmental sample of NY physicians, OIG found that [13] chemotherapy drugs could be purchased at amounts below the established AWP, and that AWP was not a reliable indicator of cost. Recommendations include that HCFA (1) define reimbursement policy to encourage "most economical means" available for physician purchase of drugs; (2) revise coding and reimbursement systems to pay for drugs based on dosage actually administered. NB: Report noted that Equicore, the TN Medicare carrier, based payments for 5 chemo drugs on physician invoice prices.
Feb. 1996	"Medicare Payments for Nebulizer Drugs" (OEI-03-94-00390)	OIG examined differences in reimbursement methodologies between Medicare and Medicaid for 3 inhalation drugs in 17 states (1/94-2/95), finding that Medicare payments were considerably higher than those from Medicaid would have been due to (1) Medicare not using a discounted AWP, and (2) Medicare not having a drug rebate program with manufacturers. Recommendations included (1) use of a discounted AWP to establish drug prices (which would require revising Medicare's claims coding system to an NDC basis); (2) pursuing legislative options to establish a rebate program or competitive bidding process; (3) use the "inherent reasonableness" authority to set charge limits (would require streamlining that authority); (4) base payment on estimated acquisition cost (EAC) (although the regional carriers -- DMERCs -- had not been successful in gathering the necessary information). NB: Report made reference to OIG intent to examine other drugs that Medicare reimburses.
May 1996	"Appropriateness of Medicare Prescription Drug Allowances" (OEI-03-95-00420)	OIG compared Medicare and Medicaid drug payment methodologies for 17 physician-administered drugs (based on Medicare 1994 allowances for those drugs), finding that Medicaid's greater use of more heavily discounted AWP, and rebates, would have afforded lower prices than Medicare was paying. Recommendations were similar to those for nebulizer drugs, above. NB: With respect to Medicaid, the report also noted that states differed in their application of payment methodologies. More states used a discounted AWP to establish reimbursements to pharmacies than they did to physicians, meaning that some states used different discounting methodologies to reimburse pharmacy-dispensed vs. physician-administered drugs. Some states handled rebates differently for physician-administered drugs than for self-administered drugs.



Jun. 1996 (a)	"Suppliers' Acquisition Costs for Albuterol Sulfate" (OEI-03-94-00393)	OIG found that Medicare allowances for albuterol sulfate substantially exceeded suppliers acquisition costs. Same recommendations as for nebulizer drugs. HCFA concurred with recommendations, but noted that OMB did not approve a 1994 survey attempt to collect acquisition cost data because of burdensome nature of the task.
Jun 1996 (b)	"A Comparison of Albuterol Sulfate Prices" (OEI-03-94-00392)	OIG found that many pharmacies surveyed charged less than the Medicare allowance for albuterol, and that 5 buying groups surveyed had negotiated prices between 56 – 70% less than Medicare's reimbursement amount. Same recommendations as for nebulizer drugs.
Apr. 1997	"Medicaid Pharmacy – Actual Acquisition Costs of Prescription Drug Products for Brand Name Drugs" (A-06-96-00030)	OIG sampled Medicaid pharmacy providers in 11 states, comparing their actual invoices for drug purchases to AWP. OIG identified an average discount of 18.3% off AWP on a national basis (CY 1994), substantially larger than many states' reimbursement policies allowed (typically a 10% discount). OIG recommended HCFA work with states to ensure that reimbursement of the "ingredient portion" of Medicaid drug purchases was more in line with OIG's findings. [NB: Based on methodology, it appears that this analysis would have included primarily, and perhaps exclusively, self-administered drugs.] The report specifically refers to the June 1996 Barrons's article comparing AWP to actual acquisition costs, noting that industry insiders joked that AWP really meant "Ain't What's Paid".
Dec. 1997	"Excessive Medicare Payments for Prescription Drugs" (OEI-03-97-00290)	OIG focused on 22 drug codes representing Medicare's largest dollar outlays in 1995, and found that program and beneficiary payments would have been lower by 29% if reimbursements were based on actual wholesale prices rather than AWP. OIG specifically noted that published AWP's bore little or no resemblance to actual wholesale prices available to the physician and supplier communities. Medicare allowances were significantly greater than prices available thru wholesalers and Group Purchasing Organizations (gpos). OIG also found inconsistency in carriers' establishing and updating Medicare drug reimbursement amounts. Recommendations included (1) basing reimbursement on a more substantial discount off AWP than 5%; (2) pursuing an actual or EAC option; establishing limits on increases in subsequent year price increases; (3) invoking the "inherent reasonableness" authority to set charge limits; (4) pursuing legislative options to establish rebates or competitive bidding; (5) standardizing reimbursement amounts for each HCPCS drug code.
May 1998	"Need to Establish Connection Between the Calculation of Medicaid Drug Rebates and Reimbursement for Medicaid Drugs (A-06-97-00052)	OIG recommended that HCFA develop and submit a legislative proposal that would require drug manufacturers participating in Medicaid's outpatient Rx drug program to <i>pay Medicaid rebates based on AWP rather than on AMP</i> as provided by statute. OIG sought to reduce the anomaly of reimbursements to pharmacies being calculated relative to AWP while rebates were based on AMP. Manufacturers were

		inconsistent in their calculation of AMP, and OIG estimated substantial savings from aligning the rebate and reimbursement calculations. OIG recognized that there were problems with AWP but felt that, with certain safeguards, the use of AWP in rebate calculations could result in its being a more “meaningful and accurate number”. HCFA did not believe that a legislative initiative was feasible, but agreed that changing from AMP to AWP would reduce an administrative burden. A March 2002 OIG report notes that President Bush’s Fiscal Year 2003 budget proposed changing the basis for calculating rebates from AMP to AWP.
Jul. 1998	“The Impact of High-Priced Generic Drugs on Medicare and Medicaid” (OEI-03-97-00510)	OIG examined 4 drugs in which Medicare reimbursements were excessive because of the inclusion of high-priced generics (i.e., higher than brand prices) in the median generic price on which reimbursement was based. Re Medicaid (FL) – OIG examined 8 drugs for which reimbursements could have been less but for (1) inclusion of high-priced generics that (2) yielded lower rebates than branded drugs. OIG recommended the exclusion of higher-priced generics from median calculations used to determine reimbursement levels (Medicare), and restrict reimbursements by Medicaid to [pre-rebate] lower-priced brand or generic drugs.
Aug. 1998	“Are Medicare Allowances for Albuterol Sulfate Reasonable?” (OEI-03-97-00292)	OIG found Medicare allowances for albuterol substantially exceeded what the VA would pay for generic albuterol in 1998, and that mail order customers would pay up to 30% less than Medicare’s allowances in 1998.
Nov. 1998	“Comparing Drug Reimbursement: Medicare and the Department of Veterans Affairs” (OEI-03-97-00293)	OIG examined 34 drug codes, for which Medicare payments were substantially greater than VA payments. In the absence of statutory reform, OIG recommended that HCFA invoke “inherent reasonableness” authority, and implement competitive bidding. HCFA noted that its DMERCs were recommending an 11% reduction in albuterol reimbursements, and that other drugs might be similarly reviewed. HCFA was subsequently challenged on the albuterol reductions, with “inherent reasonableness” authority put on hold.
Jun. 2000 (a)	“Medicare Reimbursement of Albuterol” (OEI-03-00-00311)	OIG compared Medicare reimbursements for albuterol with those of Medicaid and the VA, as well as with prices paid by chain and internet pharmacies. As with earlier reports, Medicare was again the outlier. Recommendations of previous reports were reiterated, with the notation that ability to invoke the “inherent reasonableness” authority had been limited by the 1999 Balanced Budget Refinement Act – GAO was to study the potential effects of using this measure before HCFA could invoke it. HCFA’s response indicated it was moving to take advantage of DOJ and NAMFCU prices provided to First Databank, and was taking other actions including establishing a competitive bidding project in TX for albuterol purchases. The First DataBank prices were considered to be “more accurate data on average wholesale prices developed for Medicaid” as a result of a DOJ



		investigation.
Jun 2000 (b)	"Medicare Reimbursement of End-Stage Renal Disease Drugs" (OEI-03-00-00020)	OIG comparison of Medicare reimbursement of five ESRD drugs with that of Medicaid and VA. Similar findings, recommendations, and HCFA responses as above, with additional emphasis placed on HCFA's seeking legislative efforts to reduce its outlays.
Jan. 2001	"Medicare Reimbursements of Prescription Drugs" (OEI-03-00-00310)	OIG compared Medicare's reimbursement for 24 drugs (physician-administered or used with a nebulizer) with that of the VA, the physician/supplier community, and Medicaid. In addition to finding Medicare payments far exceeded those of the comparators, OIG noted that local Medicare carriers were not establishing consistent reimbursement amounts for certain drugs. In its response, HCFA noted that efforts to have its carriers use the DOJ's First DataBank AWP had been hampered by legislation (H.R. 5543) that put a freeze on changes to AWP in use by Medicare as of 9/1/00.
Jul. 2001	"Cost Containment of Medicaid HIV/AIDS Drug Expenditures" (OEI-05-99-00611)	OIG compared Medicaid's net unit cost for antiretrovirals to that of other federal purchasers, and found that Medicaid paid from 5% - 33% more than the comparators. Part of the difference was attributed to different federally mandated formulae, however the discussion highlighted problems in determining an EAC, and the role of AWP manipulation in contributing to excessive payments.
Aug. 2001	"Medicaid Pharmacy - Actual Acquisition Costs of Brand Name Prescription Drug Products (A-06-00-00023)	OIG examined pharmacy actual acquisition costs of brand name drugs for 8 states, determining that the average discount off AWP for branded drugs was 21.84% for 1999 (an increase of 19.3% from their 1997 analysis for 1994 prices). However, this discount was greater than the discount allowed under most states' reimbursement policies. While AWP was not the basis for EAC in all states it was nonetheless predominant, with the average discount on a national basis being 10.31% of AWP. (OIG also compared WAC to actual acquisition price for pharmacies, and determined that invoice prices were, on a national basis, 1.81% below WAC.)
Mar. 2002 (a)	"Excessive Medicare Reimbursement for Ipratropium Bromide" (OEI03-01-00041)	OIG compared Medicare reimbursements (based on AWP) for this inhalant product to prices paid by the VA, and to catalog and wholesaler/supplier prices. Medicare paid considerably more than any of the comparators, even though payments to 23 suppliers (accounting for 60% of Medicare payments) were presumably to outfits purchasing large quantities of the product (and thus able to attract manufacturer discounts).
Mar. 2002 (b)	"Medicaid Pharmacy - Actual Acquisition Cost of Generic Prescription Drug Products (A-06-01-00053)	OIG examined pharmacy actual acquisition costs of generic drugs in 8 states, determining that the average discount off AWP for generic drugs was 65.93% for 1999 (an increase of 55% from their 1997 analysis of 1994 prices.) However, states' reimbursement methodologies did not allow them to capture much of this discount, and OIG recommended that reimbursements for ingredient costs be brought more in line with pharmacy acquisition costs. Since some states used WAC to determine reimbursement, OIG also examined WAC

		relative to acquisition cost, finding invoice prices averaging 30.55% below WAC. OIG felt that WAC was not a true wholesale acquisition cost and was significantly higher than actual acquisition costs for generic drugs. OIG also cited a 1984 report in which it found that pharmacies purchased drugs at 15.9% below AWP, and a 1989 report showing a 15.5% discount. However, these reports combined brand and generic drugs. The cover letter to this report references the Bush FY 2003 proposal to use AWP rather than AMP in rebate calculations.
Sep. 2002	"Medicaid Pharmacy – Additional Analyses of the Actual Acquisition Cost of Prescription Drug Products (A-06-02-00041)	A follow-up to the March 2002 report, OIG extended their analysis of discounts off AWP for additional drug categories, including single and multiple source innovator drugs, and drugs with and without federal upper limits (FULs). OIG found wide variation in prices paid by pharmacies, with average discounts off AWP ranging from 17.2% for single source innovator drugs to 72.1% for multiple source drugs with upper limits. OIG recommended that for states that continued to reimburse for drugs based on AWP, a four-tiered reimbursement methodology be introduced that better captured the within-category fluctuations in actual discounts: (1) single source innovator drugs; (2) all drugs without FULs; (3) multiple source drugs without FULs; (4) multiple source drugs with FULs. Without evaluating CMS' FUL prices, OIG also observed that drug manufacturers appeared to provide steeper discounts off AWP for drugs with FUL listings. Finally, OIG reiterated their recommendation that AWP be substituted for AMP in calculating rebates due from manufacturers.
Jan. 2004 (a)	"Update: Excessive Medicare Reimbursement of Albuterol" (OEI-03-03-00510)	Another comparison of Medicare reimbursements vs. Medicaid payments for albuterol. Findings similar to above; some additional discussion about DMERCs charged with determining reimbursement methodologies in their respective regions, based on Medicare methodology.
Jan. 2004 (b)	"Medicare Reimbursement for Lupron" (OEI-03-03-00250)	OIG discusses a "local medical review policy ("LRMP") whereby Medicare carriers apply a "least costly alternative" standard in determining reimbursement. Specifically, OIG reviewed jurisdictions' application of that standard with respect to Lupron being covered at the less expensive Zoladex price, and found that not all jurisdictions were applying the standard.
Jan. 2004 ©	"Update: Excessive Medicare Reimbursement for Ipratropium Bromide" (OEI-03-03-00520)	Update of 2002 OIG comparison of Medicare reimbursements for this inhalant relative to those of Medicaid and the VA.
Sep. 2004	"Variation in State Medicaid Drug Prices" (OEI-05-02-00681)	For 28 drugs, OIG found considerable variation across states in reimbursement rates, with prices varying more for the 10 non-innovator drugs than for the 18 innovator products. Comparable estimated acquisition cost formulae (e.g., AWP-10%) might still yield very different prices. There were also

		differences in setting "U&C" charges as well as MAC.
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All reports accessed through [www.oig.hhs.gov/reports.htm](http://www.oig.hhs.gov/reports.htm).

## Attachment C

### Other Uses of AWP

Manufacturers frequently sponsor or support pharmacoeconomic studies that compare the cost-effectiveness of alternative medical treatments, sometimes among pharmaceuticals, and other times involving comparisons of therapies combining pharmaceutical and non-pharmaceutical components. In the well-known National Institutes of Health convened consensus guideline compendium for conducting cost-effectiveness studies, the following recommendation is made concerning what prices should be used when evaluating pharmaceutical costs:

“Because the class of drugs must break even – have revenues large enough to cover R&D, production and distribution costs – prevailing transactions prices will usually act as a serviceable way to value consumption of the drugs. The Average Wholesale Price (AWP), which approximates prices in discount pharmacies, is one source of such information (Drug Topics Red Book, 1994).”<sup>299</sup>

Note that to the extent AWP's approximate the cash prices paid by retail pharmacy customers (which is not an uncommon assumption, as I noted in the main text), this recommended use of AWP is understandable. However, because cash prices at retail pharmacies are typically much greater than pharmacy reimbursements received from third party payors (plus patient copayments), and since cash transactions are a small and declining portion of all retail transactions (less than 15% of prescriptions in 2002 and 2003),<sup>300</sup> the recommended guideline use of AWP overstates average prescription drug costs to third party payors. Hence, to the extent

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<sup>299</sup> Marthe R. Gold, Louise B. Russell, Joanna E. Siegel and Milton C. Weinstein, eds., *Cost-Effectiveness in Health and Medicine*, New York: Oxford University Press, 1996, p. 195. A summary of these guidelines was published by the authors under the title “Recommendations for Reporting Cost-Effectiveness Analysis”, *Journal of the American Medical Association* 276, No. 16 (1996), pp. 1339-1341.

<sup>300</sup> Stephen W. Schondelmeyer and Marian V. Wrobel, *Medicaid and Medicare Drug Pricing: Strategy to Determine Market Prices*, Abt Associates Inc., August 30, 2004, p. 12.

manufacturers “artificially inflate” AWP, other things equal, the measured cost-effectiveness of their products is likely to be reduced.

Evidence suggests drug manufacturers are increasingly employing economic messages in prescription drug advertisements in medical journals. A recent study reports that the proportion of ads with economic content in six leading general medical and specialty journals increased between 1990 and 1999.<sup>301</sup> When assertions were made that a drug was “less expensive” or “costs less”, 92% of the advertisement provided supporting evidence. According to the authors:

“Supporting evidence pertained mostly to the average wholesale price of drugs (51.1%) or to published drug prices in the Red Book (38.7%). Other sources included ‘data on file’ (9.5%) and references to published studies (6.6%).”<sup>302</sup>

Of related interest is the FDA’s policy on what price comparisons it permits in manufacturers’ promotional material, and what types of economic claims the FDA considers false or misleading.

One recent analysis of FDA actions analyzed all public letters sent by the FDA’s Division of Drug Marketing, Advertising and Communications (“DDMAC”) to drug companies in which promotional violations involving economic claims were cited. Of the 28 warning letters and notices of violation between January 1997 and December 2001, five (17.9%) involved misleading price comparisons.<sup>303</sup> According to the authors, two DDMAC citations involving misleading price comparisons were as follows, with both explicitly lacking support by reference to AWP:

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<sup>301</sup> Peter J. Neumann, Kara Zivin Bambauer, Vijay Ramakrishnan, Kate A. Stewart and Chaim M. Bell, “Economic Messages in Prescription Drug Advertisements in Medical Journals”, *Medical Care*, 40:9, 2002, pp. 840-845.

<sup>302</sup> Peter Neumann et al. [2002], *supra*, p. 842. A footnote appended after the words “Red Book” referenced: “Drug topics, Red Book. Montvale, NJ: Medical Economics; 1999.”

<sup>303</sup> Kate A. Stewart and Peter J. Neumann, “FDA Actions against Misleading or Unsubstantiated Economic and Quality-of-Life Promotional Claims: An Analysis of Warning letters and Notices of Violation”, *Value in Health*, 5:4, 2002, pp. 390-397.

“...comparative pricing claims are misleading because they lack adequate context...The cost effectiveness claim is misleading because the claim is not supported by reference to AWP.”

“The comparative price/cost conclusion of a ‘47% difference’ is misleading because the above price/cost comparison is based on an undefined time frame and therefore the conclusion of a 47% difference suggests a greater savings than what is supported by AWP data.”<sup>304</sup>

Other uses of “artificially inflated” AWP are likely to have negative impacts on pharmaceutical manufacturers. Critics of the pharmaceutical industry, such as Families USA, frequently criticize the industry for raising its prices, and document such price increases by publishing annual changes in manufacturers’ AWP.<sup>305</sup> To the extent AWP are “artificially inflated”, manufacturers are likely to face increased amounts of adverse publicity. Finally, health data information firms such as IMS Health produce data on, among other costs, the marketing costs of prescription drug manufacturers. Critics of the industry frequently cite the pharmaceutical industry as having excessive marketing costs.<sup>306</sup> By convention, IMS Health reports that approximately one half of pharmaceutical “detailing” promotional costs (office visits by sales representatives to physicians) consist of free samples left physicians. These free sample costs are calculated by valuing the free samples at average retail value. It is my understanding

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<sup>304</sup> Stewart and Neumann, “Analysis of FDA Regulatory Actions” [2002], *supra*, p. 397.

<sup>305</sup> See, for example, *Sticker Shock: Rising Prescription Drug Prices for Seniors: A Report by Families USA*, June 2004, available online at [www.familiesusa.org/site/DocServer/Sticker\\_Shock.pdf?docID=3541](http://www.familiesusa.org/site/DocServer/Sticker_Shock.pdf?docID=3541). Accessed 1/23/05. Notes to Table 1 refer to Medi-Span’s MDDB Select, published by Medi-Span, as a data source. An earlier Families USA publication provides more details: see *Worthless Promises -- Drug Companies Keep Boosting Prices: A Report by Families USA Foundation*, March 1995. On page 9 it is stated: “The price increase data in this report is based on price increases in average wholesale prices. This list price is set by manufacturers as the suggested price a wholesaler should charge a retail pharmacy. Since nearly all retail pharmacies use the AWP to determine a prescription’s retail price, this price provides an accurate reflection of the price increases that consumers face when they purchase prescriptions in retail pharmacies and pay out of pocket. The Medi-Span Master Drug Database of drug prices provided average wholesale price information for the most frequently dispensed outpatient strengths and package sizes of drugs.”

<sup>306</sup> See, for example, Marcia Angell, *The Truth About the Drug Companies: How They Deceive Us and What To Do About It*, New York: Random House, 2004. See, for example, chs. 8 and 9. On p. xviii, she calls the pharmaceutical industry “primarily a marketing machine to sell drugs of dubious benefit”.

that the AWP is used as the measure of average retail value, but I have not been able to confirm that.<sup>307</sup>

Finally, although to date the recommendation has not been adopted, the Department of Health & Human Services, Office of Inspector General, has endorsed the CMS' legislative proposal that Medicaid prescription drug rebates from drug manufacturers be calculated on the basis of AWP rather than the average manufacturer's price ("AMP"). Unless the rebate proportion would change as well, such a policy change would likely "result in AWP's that more closely reflect the actual acquisition cost of a given drug."<sup>308</sup>

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<sup>307</sup> Meredith B. Rosenthal, Ernst R. Berndt, Julie M. Donohue, Richard G. Frank and Arnold M. Epstein, "Promotion of Prescription Drugs to Consumers", *New England Journal of Medicine*, 346(7), February 14, 2002, pp. 498-503.

<sup>308</sup> Office of Inspector General, *Medicaid Pharmacy – Additional Analyses of the Actual Acquisition Cost of Prescription Drug Products*, Report A-06-02-00041, September 2002, p. 11.  
Attachment D

## Attachment D

Ownership of Top PBMs – Quarter 1, 1999

Rank	PBM Name	Owner Type (a)	Comments
1	Merck Medco Managed Care	Pharmaceutical firm	Medco Containment Services founded as a mail order prescription firm, substantial growth after investment by Martin Wygod (1983); purchased by Merck in 1993; spun off from Merck in 2003
2	PCS Health Systems	Retail Chain	Eli Lilly purchased PCS, the nation's largest managed pharmaceutical care company, from McKesson in 1994 and then sold to Rite Aid in 1998. Sold by Rite Aid to Advance Paradigm in 2000.
3	Diversified Pharmaceutical Services	in transition to PBM parent from pharmaceutical firm	Founded by United Healthcare, then incorporated in 1988; sold to SmithKline Beecham in 1994. Acquired by Express Scripts in 1999.
4	Express Scripts/Value Rx	Independent	Founded in 1986, brought public in 1992 after being spun out of New York Life. Acquired Value Rx from Columbia / HCA Healthcare Corporation in 1998. Acquired DPS from SmithKline Beecham in 1999.
5	Aetna Pharmacy Management	Insurance company	
6	Advance Paradigm	Independent	Incorporated in July 1993 as a wholly owned subsidiary of Advance Health Care, which then merged into Advance Paradigm before a public offering in 1996. Acquired Integrated Prescription Solutions in 1999 and PCS Health Systems in 2000. Purchased by Caremark in 2004.
7	Wellpoint Pharmacy Management	Health Plan	Founded in 1992 to operate Blue Cross of California's managed care business, spun off in 1993 as a separately traded public entity. Became part of Anthem, Inc. in 2004, with Anthem adopting the Wellpoint name.
8	RxPrime	Insurance company	Cigna's managed PBM, formed in 1992
9	Caremark Prescription Services	Independent	Established as a division of Baxter Healthcare Corp. in 1985. Purchased Prescription Health Services in 1991; spun off from Baxter in 1992.



10	Prescription Solutions	Independent	Founded in 1993 by pharmacists for managed care.
11	National Prescription Administrators	Independent	Originally founded and operated by pharmacists (c. 1978); acquired by Express Scripts in 2002.
12	ProVantage	Retailer	Launched in 1993 as a ShopKo (discount chain) subsidiary; purchased by Merck Medco in 2000.
13	MedImpact / MedCare	Privately held	MedImpact was founded in 1989; considered the "largest privately held PBM in the nation". MedCare is MedImpact's national formulary.
14	Prudential Pharmacy Management	Insurance company	
15	Prime Therapeutics	Independent	Created in 1998 by merger of Pharmacy Gold Inc. and ProPar Services; in 2005 several Blue Cross / Blue Shield plans joined together to acquire an ownership interest in Prime.
16	Eagle Managed Care	Retail chain	Rite Aid's PBM subsidiary, which merged with PCS Health Systems when Rite Aid purchased that firm in 1999.
17	Proserve	n/a	Name linked with Wellpoint but other information not found.
18	RxAmerica	Retail chain	Began managing Rx programs ~20 years ago as American Drug Stores (now Albertsons); officially formed as a PBM in 1994. Longs Drug Stores and American Drug Stores merged PBM operations in 1997, calling the venture RxAmerica.
19	PharmaCare Network	Retail chain	Founded in 1994; a wholly owned subsidiary of CVS
20	RESTAT	Wholesaler	Founded c. 1985; part of The F. Dohmen Company, a "nationally recognized pharmaceutical service, distribution, and software consultant".

## (a) At time of ranking

n/a: no information available

Source of PBM ranking: The Role of PBMs in Managing Drug Costs: Implications for a Medicare Drug Benefit. Prepared by Mathematica Policy Research, Inc. for The Henry J. Kaiser Family Foundation, January 2000. Available online at [www.pharmacy.ca.gov/publications/pbm\\_kff\\_role.pdf](http://www.pharmacy.ca.gov/publications/pbm_kff_role.pdf), last accessed 1/28/05.

Other websites consulted for additional information on each ranked PBM are listed on the next page.

## Websites accessed 1/28/05:

[www.utsystem.edu/egi.newsletter](http://www.utsystem.edu/egi.newsletter)  
[www.primetherapeutics.com/about/history.htm](http://www.primetherapeutics.com/about/history.htm)  
[www.medimpact.com/About\\_MedImpact/default.asp?subpage=background](http://www.medimpact.com/About_MedImpact/default.asp?subpage=background)  
[www.restat.com/information/index.cfm](http://www.restat.com/information/index.cfm)  
<http://sec.edgar-online.com/1996/09/30/00/0000912057-96-021465/Section11.asp>  
[www.caremark.com/wps/portal/s.155/3359?cms=CMS-2-003599](http://www.caremark.com/wps/portal/s.155/3359?cms=CMS-2-003599)  
[www.anthem.com/jsp/antiphona/apm/primary.jsp?secp=AboutUs](http://www.anthem.com/jsp/antiphona/apm/primary.jsp?secp=AboutUs)  
[www.rxsol.com/a/about/aboutus.asp](http://www.rxsol.com/a/about/aboutus.asp)  
[www.pharmicare.com/about/index.jsp](http://www.pharmicare.com/about/index.jsp)  
[www.delta-hq.org/publications/AllAboutCVS.pdf](http://www.delta-hq.org/publications/AllAboutCVS.pdf)  
[www.rxamerica.com/about\\_us\\_company\\_overview.htm?page=us](http://www.rxamerica.com/about_us_company_overview.htm?page=us)  
[www.wellpoint.com/business/company\\_history.asp](http://www.wellpoint.com/business/company_history.asp)

## Websites accessed 1/29/05:

[www.perfectvisionresources.com/articles/contact-lenses/contact-lenses-article-858.htm](http://www.perfectvisionresources.com/articles/contact-lenses/contact-lenses-article-858.htm)  
[www.pbmi.com/pbmnews/V5N3IND.htm](http://www.pbmi.com/pbmnews/V5N3IND.htm)  
[www.sec.gov/Archives/edgar/data/1012956/0000912957-96-013211.txt](http://www.sec.gov/Archives/edgar/data/1012956/0000912957-96-013211.txt)  
<http://biz.yahoo.com/ic/54/54752.htm>  
[www.stltoday.com/business/special/pdtop5003.nsf/O/2EB88E53488EF5586256D2B0000280F?OpenDocument](http://www.stltoday.com/business/special/pdtop5003.nsf/O/2EB88E53488EF5586256D2B0000280F?OpenDocument)  
[www.seniorjournal.com/NEWS/Health/3-07-14blackstone.htm](http://www.seniorjournal.com/NEWS/Health/3-07-14blackstone.htm)  
[www.cigna.com/general/about/history/html](http://www.cigna.com/general/about/history/html)  
[www.riteaid.com/company\\_info/press/press\\_show.php/item\\_nbr/265/cat/national](http://www.riteaid.com/company_info/press/press_show.php/item_nbr/265/cat/national)  
[http://parketcenter.johnson.cornell.edu/docs/cayuga\\_fund/1999\\_2000/research\\_reports/esrx.pdf](http://parketcenter.johnson.cornell.edu/docs/cayuga_fund/1999_2000/research_reports/esrx.pdf)  
[www.cms.gov/researchers/reports/2001/cms.pdf](http://www.cms.gov/researchers/reports/2001/cms.pdf)  
<http://static.highbeam.com/forbes/april151991/drugsbymailmartinwygodmedcocontainmentservicesinc/>  
[www.medimpact.com/About\\_MedImpact/default.asp?subpage=online&service=formulary\\_lookup](http://www.medimpact.com/About_MedImpact/default.asp?subpage=online&service=formulary_lookup)  
[www.lilly.com/about/responsible/profile\\_index.html](http://www.lilly.com/about/responsible/profile_index.html)  
[www.findarticles.com/p/articles/mi\\_m3374/is\\_n3\\_v17/ai\\_16541609](http://www.findarticles.com/p/articles/mi_m3374/is_n3_v17/ai_16541609)  
[www.unitedhealthgroup.com/about/inn.htm](http://www.unitedhealthgroup.com/about/inn.htm)

# **Exhibit 3A**

Tina Wong

Helena, Montana

September 28, 2004

Page 1

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS

-o0o-

IN RE: PHARMACEUTICAL )  
INDUSTRY AVERAGE ) MDL No. 1456  
WHOLESALE PRICE )  
LITIGATION ) No.  
----- ) 01-CV-12257-PBS  
This Document Relates to )  
All Actions )  
Defendant. )

September 28, 2004

DEPOSITION OF TINA WONG

Deposition of TINA WONG, taken on behalf of  
Johnson & Johnson, at 404 Fuller Avenue, Helena,  
Montana, commencing at 2:00 P.M., on Tuesday, September  
28, 2004, before LESIA J. MERVIN, CSR No. 4753, RMR,  
Certified Realtime Reporter.

Tina Wong

Helena, Montana

September 28, 2004

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1 prescription drug pricing reporters?

2 A. Can you give me an example of one?

3 Q. Well, pricing reporter would be like the  
4 Red Book or the First Data Bank?

5 A. You know, in my position I don't,  
6 because our pharmacy benefit manager does the pricing  
7 for us. So I don't, but I do know as a plan, you know,  
8 we do use, you know, several different pricing methods.

9 Q. Okay. What about any other trade  
10 periodicals or anything like that?

11 A. I do. I get Drug Topics. I can't think  
12 of them when I'm sitting here. Managed Care Executive.  
13 I do get a couple more. If you'd like me to follow up  
14 with that information, I can.

15 Q. That's fine. Do you ever receive any  
16 transmittals or documents from HCFA or previously CMS?

17 A. That is not something I handle in my  
18 job.

19 Q. Okay. You mentioned that the -- that  
20 Blue Cross Blue Shield of Montana does receive some  
21 pricing services, but that you don't personally receive  
22 them?

Tina Wong

September 28, 2004

Helena, Montana

Page 18

1 A. Correct.

2 Q. Do you have knowledge of which pricing  
3 services?

4 A. You know, I do know that we do utilize  
5 First Data Bank primarily, and that we also utilize Red  
6 Book.

7 Q. Do you have any understanding of what  
8 particular data is reported in the First Data Bank data  
9 that you receive and in the Red Book that you receive  
10 as an organization?

11 A. I know that -- well, we receive the big  
12 book, and I have, you know, I have looked at both of  
13 those. To be honest with you, I know that there's, you  
14 know, J codes and NDC and AWP pricing in those. But  
15 it's been quite sometime since I viewed one. So I know  
16 there's other material in there, too.

17 Q. Are you familiar with the term WAC?

18 A. I am.

19 Q. Are you aware if that price appears in  
20 either the First Data Bank or the Red Book?

21 A. You know, I don't remember.

22 Q. Are you a member in any industry or

Tina Wong

September 28, 2004

Helena, Montana

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1 I, LESIA J. MERVIN, a Certified Shorthand.  
2 Reporter for the State of California, do hereby  
3 certify: That prior to being examined, the witness  
4 named in the foregoing deposition, was by me duly sworn  
5 to testify as to the truth, the whole truth, and  
6 nothing but the truth pursuant to Section No. 2093 of  
7 the Code of Civil Procedure;

8 That said deposition was taken before me at  
9 the time and place therein set forth, and was taken  
10 down by me in shorthand and thereafter reduced to  
11 typewriting via computer-aided transcription under my  
12 direction;

13 I further certify that I am neither counsel  
14 for, nor related to, any party to said action, nor in  
15 anywise interested in the outcome thereof.

16 IN WITNESS WHEREOF, I have hereunto  
17 subscribed my name this \_\_\_\_\_ day of June, 2004.

18

19

20

21 LESIA J. MERVIN

22 CSR No. 4753, RMR, CRR

# **Exhibit 4A**



UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS

NEW ENGLAND CARPENTERS HEALTH  
BENEFITS FUND, PIRELLI ARMSTRONG  
RETIREE MEDICAL BENEFITS TRUST,  
TEAMSTERS HEALTH & WELFARE FUND  
OF PHILADELPHIA AND VICINITY, and  
PHILADELPHIA FEDERATION OF  
TEACHERS HEALTH AND WELFARE FUND,

Plaintiffs,

Case No. 1:05-CV-11148-PBS

v.

FIRST DATABANK, INC., a Missouri  
corporation, and MCKESSON CORPORATION,  
a Delaware corporation,

Defendants.

**DECLARATION OF GREGORY MADSEN**

I, Gregory Madsen, declare as follows:

1. I am the Senior Vice President of Retail Services at Caremark Inc. ("Caremark") and have held this position since May 2004. From November 1999 through April 2004, I served as the Vice President of Retail Strategies at Caremark. I have personal knowledge of the facts set forth in this declaration. My deposition was previously taken in the *In re Pharmaceutical Industry Average Wholesale Price Litigation*, MDL No. 1456.

2. Caremark is a pharmacy benefit management company ("PBM") that, among other things, purchases services from pharmacies and resells those services to Caremark's clients, which include third party payors of prescription drug benefits. As Senior Vice President of Retail Services and Vice President of Retail Strategies, I have been responsible for negotiations of Caremark's contracts with pharmacies and establishing pharmacy networks to provide services to Caremark's

clients. My objective in negotiating Caremark's contracts with pharmacies has always been to get Caremark the best pricing terms available in light of competition in the market.

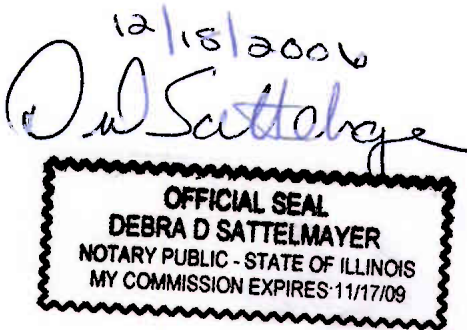
3. I understand that for branded drugs, the "spreads" or ratios between WAC and AWP were historically 20% for some drugs and 25% for others. In approximately the last quarter of 2002, I learned from someone in Caremark's finance department that the spreads on a large number of brand name drugs increased from 20% to 25%. These increased spreads were one of the factors I considered in negotiating Caremark's contracts with pharmacies.

I declare under penalty of perjury under the laws of the United States that the foregoing is true and correct.

Executed this 18 day of December, 2006, in Northbrook, IL.

By:

  
Gregory Madsen



# **Exhibit 6A**

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS

NEW ENGLAND CARPENTERS HEALTH  
BENEFITS FUND, PIRELLI ARMSTRONG  
RETIREE MEDICAL BENEFITS TRUST,  
TEAMSTERS HEALTH & WELFARE FUND  
OF PHILADELPHIA AND VICINITY;  
PHILADELPHIA FEDERATION OF  
TEACHERS HEALTH AND WELFARE FUND;  
DISTRICT COUNCIL 37, AFSCME-HEALTH  
& SECURITY PLAN; JUNE SWAN;  
MAUREEN COWIE and BERNARD GORTER,

Plaintiffs,

v.

FIRST DATABANK, INC., a Missouri  
corporation, and MCKESSON CORPORATION,  
a Delaware corporation,

Defendants.

Case No. 1:05-CV-11148-PBS

**DECLARATION OF EDWARD IGNACZAK**

I, Edward Ignaczak, declare as follows:

1. I have worked for Express Scripts ("ESI"), or a company acquired by ESI, for approximately 15 years. I have held the position of Senior Vice President-Sales and Account Management since January, 2003. Prior to holding this position, I was the Vice President and General Manager, National Accounts Division, from April, 1998 to January, 2003.
2. During the course of my employment with ESI, I have had responsibilities for contracting with clients and have participated in numerous negotiations with potential and existing ESI clients. I am familiar with the facts set forth in this Declaration based upon my personal knowledge and discussions with other knowledgeable ESI employees.
3. ESI is one of the largest pharmacy benefit managers ("PBM") in North America. ESI provides a full range of pharmacy benefit management services, including retail drug card programs, home delivery pharmacy services, drug formulary management programs, Specialty services, and other clinical management programs for thousands of client groups such as employers, health plan sponsors, unions, coalitions, insurance companies, HMOs, and third party administrators (the term "Contracting Party" or "Contracting Parties" collectively refers to an ESI client or clients who contract with ESI for pharmacy benefit management services).
4. Contracting Parties enter into contracts with ESI which specify the various services and programs that ESI provides to the Contracting Party. The various services and programs that ESI offers to Contracting Parties enhance safety and assist them in managing the costs of providing prescription drug benefits to individuals covered by the health plans for which the Contracting Party has responsibility. ESI provides adjudication of prescription drug claims and other services (at the Contracting Party's option) including, but not limited to, (a) access to networks of retail pharmacies with whom ESI has independently negotiated contracts for

prescription drug services, (b) formulary services, (c) benefit design consultation; (d) drug utilization review (“DUR”) services, (e) disease management, (f) compliance and therapy management programs, and (g) home delivery pharmacy services provided through an affiliate (mail order pharmacy) of ESI.

5. In 2005, ESI processed 437 million network pharmacy claims and dispensed 40 million home delivery pharmacy prescriptions.

6. ESI independently contracts with pharmaceutical manufacturers for rebates on certain prescription drugs dispensed by pharmacies to the participants of the benefit plans offered by or through the Contracting Parties. Rebates are a factor in the overall prescription drug cost savings that ESI offers to Contracting Parties. Pharmaceutical manufacturers pay rebates to ESI based on various factors or formulas, including a percentage of the AWP for certain drugs. If the rebateable AWP for a certain drug increases, the rebate paid on that drug may also increase. The percentage of rebates that ESI pays to Contracting Parties varies according to the contractual terms negotiated by each Contracting Party; it can range anywhere between zero to in excess of 100% in the case of a negotiated set or guaranteed rebate amounts.

7. In addition to ESI, there are several other large PBM companies and many smaller PBM companies with whom Contracting Parties can choose to contract with for services. These competitors include large, national companies, including Medco Health Solutions, Inc. and Caremark (which merged with AdvancePCS in 2004), as well as health insurers and HMOs that have their own PBM capabilities. ESI competes with these other entities to obtain (or retain) business from a Contracting Party. Some Contracting Parties have begun contracting with ESI after terminating a contract with one of ESI’s competitors. Competition for business is very high between the PBMs.

8. One of the primary ways in which ESI and other PBMs compete to obtain (or retain) business from a Contracting Party is through a Request for Proposal (“RFP”) process. Through this process, Contracting Parties consider a multitude of factors in comparing the bids and proposals from competing PBMs, and very often use highly skilled and experienced professional consultants to advise and assist them with analyzing competing proposals and using these proposals in negotiations with PBMs to obtain the best terms to meet a plan’s individual needs.

9. Price is influenced by a multitude of terms in a contract. Different Contracting Parties have prioritized different terms in their negotiations with ESI. For example, some Contracting Parties may elect to receive a smaller discount on pricing in the retail pharmacy network or mail pharmacy in exchange for receiving a larger share of the pharmaceutical manufacturer rebates paid to ESI. Other clients, however, choose to receive a greater discount on pricing in the retail pharmacy network or mail pharmacy in exchange for receiving none or a smaller share of the rebates paid to ESI.

10. Some client contracts have “pass-through” pricing provisions whereby Contracting Parties pay the same price for drugs that ESI pays to pharmacies for these drugs. In other contracts, the payments made by Contracting Parties are based on negotiated price terms that may vary from the prices ESI pays to pharmacies for the same prescription drugs.

11. A component of the payments made by Contracting Parties may be calculated through a percentage discount off average wholesale prices (AWPs) for drugs. ESI generally uses AWPs published by First DataBank to calculate the price of a drug, although the source of the AWP may vary depending on the terms of a client contract. Some Contracting Parties have

their own subscriptions to one or more publishers of AWP's so that they may conduct audits to ensure that ESI is processing claims as agreed to under the contract.

12. In addition to the pricing dimensions, PBMs compete to obtain (or retain) business from Contracting Parties based on non-price dimensions important to some Contracting Parties, such as the extent of the retail pharmacy networks offered, mail order pharmacy capabilities, and outcomes assessments. Some Contracting Parties are willing to receive a smaller discount on pricing in exchange for better non-price contract terms.

13. Contracting Parties have consistently demanded and obtained better pricing and/or services from ESI through the RFP and renegotiation processes. Some clients have obtained better pricing terms, including steeper discounts off AWP, during a contract term.

14. Formularies list the preferred drugs for the Contracting Parties' benefit plans. Some Contracting Parties select from a number of different formularies developed by ESI, while others may choose to develop their own customized formulary to meet a specific benefit design.

15. Historically, many Contracting Parties selected a plan design that included an open formulary in which all drugs were equally covered by the plan. Since the late 1990s, an increasing number of Contracting Parties have selected formulary arrangements that contribute to cost management while meeting therapeutic needs, such as implementing formularies with three or four tiers of co-payments, increasing the variability in the amount of the co-payments, or implementing closed formularies in which benefits are available only for drugs listed on the formulary. The amount of the co-payments made by plan participants varies from plan to plan, as determined by the individual Contracting Parties, and percentage co-payments can be based on a variety of formulas, some of which do not depend on AWP.



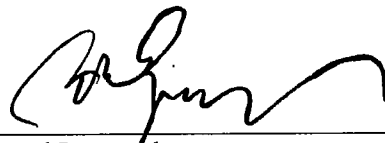
16. Contracting parties bargain energetically to control their price per-member per-month costs. The overall price quoted by ESI for its services generally is comprised of multiple components many of which may be traded off to meet the individual Contracting Party's needs objectives, including the price for the drugs dispensed, the dispensing fees, the administrative or reporting fees, and the amount of rebates paid to Contracting Parties.

17. To establish the pharmacy networks that support the plan participants of ESI's clients, ESI contracts with pharmacies that dispense drugs to these plan participants. ESI's primary objectives in pharmacy contract negotiations are to achieve the best terms that allow ESI to offer competitive pricing and services to its clients.

18. ESI has renegotiated pharmacy contracts to obtain steeper discounts both before, during, and at the end of a contract term when available in the current market conditions. Since 2002, there has been a trend of increasing discounts off AWP in the payment terms contained in ESI's pharmacy contracts.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on this 23rd day of January, 2007.

A handwritten signature in black ink, appearing to read 'Edward Ignaczak', written over a horizontal line.

Edward Ignaczak

# **Exhibit 6B**

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS

NEW ENGLAND CARPENTERS HEALTH  
BENEFITS FUND, PIRELLI ARMSTRONG  
RETIREE MEDICAL BENEFITS TRUST,  
TEAMSTERS HEALTH & WELFARE FUND  
OF PHILADELPHIA AND VICINITY;  
PHILADELPHIA FEDERATION OF  
TEACHERS HEALTH AND WELFARE FUND;  
DISTRICT COUNCIL 37, AFSCME HEALTH  
& SECURITY PLAN; JUNE SWAN;  
MAUREEN COWIE and BERNARD GORTER,

Plaintiffs,

v.

FIRST DATABANK, INC., a Missouri  
corporation, and MCKESSON CORPORATION,  
a Delaware corporation,

Defendants.

Case No. 1:05-CV-11148-PBS

---

**DECLARATION OF CHRISTINA F. MACINSKI**

I, Christina F. Macinski, declare as follows:

1. I have worked for Express Scripts (“ESI”) for over 15 years and have held the position of Vice President of Pricing and Analytics since December 2001. I am fully familiar with the facts set forth in this Declaration based upon my personal knowledge, research and discussions with other knowledgeable ESI employees.

2. ESI is a pharmacy benefit management company (“PBM”). ESI provides services to entities such as employers, health plan sponsors, unions, coalitions, insurance companies, HMOs, and third party administrators (“Contracting Party” or “Contracting Parties” refers to any ESI client or clients who contract with ESI for pharmacy benefit management services).

3. In the first quarter of 2002, ESI observed that the average increase in the average wholesale price (“AWP”) as published by First DataBank (“FDB”) for certain prescription drugs was higher than in previous years. About this time, some of ESI’s Contracting Parties also advised ESI that they had noticed or heard about this increase from pharmaceutical manufacturers and asked ESI to investigate. *See, e.g.*, Exhibit A, ESI-414-00001794.

4. ESI contacted FDB in March 2002 and was advised that the increase in FDB’s AWP’s occurred in part due to routine increases in drug prices at the beginning of the year. AWP generally is adjusted when the wholesale acquisition cost (“WAC”) of a drug increases, which normally occurs in January. Exhibit B, ESI-414-00001802. Some AWP’s, however, increased without an underlying increase in WAC. Exhibit C, ESI-414-00001807-1808. In those instances, FDB advised that it applied a 25% markup over the WAC. Exhibit B, ESI-414-00001802; Exhibit C, ESI-414-1807-1808. FDB advised that it believed that it was necessary to increase the ratio to establish a more consistent relationship between WAC and AWP across branded products. It also advised that the change was prompted by several factors, including

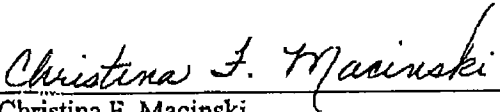
mergers between drug companies and the need to establish more pricing stability in Medicare and Medicaid. Exhibit C, ESI-414-00001807-1808, Exhibit B, ESI-414-00001802, Exhibit D, ESI-414-00001828. FDB informed ESI that ESI could release information about these increased ratios to anyone. Exhibit B, ESI-414-00001802.

5. In April 2002, ESI began to notify Contracting Parties of the increase in AWP's and the increase in the WAC-AWP ratios used by FDB for certain drugs. *See, e.g.*, Exhibit E, ESI-414-00003695-3696; Exhibit F, ESI-414-00003722-00003728; Exhibit G, ESI-414-00001857-1858; Exhibit H, ESI-414-00001859-1860; Exhibit I, ESI-414-00001861-1862; Exhibit J, ESI-414-00001864-1865; Exhibit K, ESI-414-00001866-1867; Exhibit L, ESI-414-00004208; Exhibit M, ESI-414-00003689-3690. ESI is continuing its efforts to locate additional communications with Contracting Parties on this issue.

6. ESI received follow up inquiries from several Contracting Parties regarding this notice. *See, e.g.*, Exhibit N, ESI-414-00001870-1874; Exhibit O, ESI-414-00004109-4110; Exhibit P, ESI-414-00003758-3759. Some Contracting Parties responded requesting additional information to assess the impact of these changes. *See, e.g.*, Exhibit F, ESI-414-00003722-00003728; Exhibit Q, ESI-414-00003858-3860; Exhibit F, ESI-414-00003722-3728.

I declare under penalty for perjury that the foregoing is true and accurate to the best of my knowledge.

Executed this 24th day of January of 2007

  
Christina F. Macinski

# **Exhibit 6V**

# DRUG TREND

## *2002 Report*

june 2003



**EXPRESS SCRIPTS®**

*Charting the Future of Pharmacy*

[www.express-scripts.com](http://www.express-scripts.com)

*The Bottom Line*

Per Member Per Year (PMPY) ingredient costs continued to rise, increasing by 18.5 percent in 2002. It is projected that PMPY drug costs will increase by 107 percent over the next five years.

**Acknowledgements:** The authors owe special thanks to the following people who provided substantial input and comments: Brian Ellis, BS; Paulo Frear, PharmD; Craig Kephart, RRT; Brenda Metherel, PhD and Suzanne Vargas, BS.



## **2002 Express Scripts Drug Trend Report**

***June 2003***

**Fred Teitelbaum, PhD  
Ruth Martinez, RPh  
Andrew Parker, MBA  
Brian Kolling, PharmD  
Yakov Svimovskiy, MA  
Chris Peterson, PharmD**

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June 2003  
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**ESI-277-00012345**

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## Preface

### Dear Reader,

Prescription drugs are used by more Americans as first-line treatments for an increasing number of diseases. In turn, as we use more drugs to treat diseases, the total cost of the prescription drug benefit grows.

This year, Express Scripts' *Drug Trend Report* summarizes the factors that are driving up the cost of prescription drug benefits and in doing so identifies several important findings:

- Generic drugs are quickly gaining market share. The generic fill rate reached 45.9 percent in the fourth quarter of 2002, and the use of generic drugs is expected to climb to more than 50 percent by 2004, if not sooner.
- Specialty drugs — primarily biotech drugs that require special handling — make up an ever-growing percentage of the prescription drug bill (including drug costs incorporated into the medical line item). Mainly used to treat rare diseases, specialty drug use is likely to rise at a rapid rate.
- Overall, prescription drug costs continue to grow at a double-digit rate, due in part to rising utilization.

Express Scripts is committed to helping plan sponsors provide prescription drugs to their employees/members. Last year, Express Scripts assisted our clients in lowering the cost of prescription drugs by 30 percent as compared to full retail price. We made prescription drugs more affordable by increasing the use of:

- Generics
- Mail service
- Low-cost formulary brand drugs

While lowering cost, we also helped to make the use of prescription drugs safer by sending out over 33 million safety warnings that resulted in almost 500,000 changes to drug therapy.

Not only has Express Scripts expanded the explanation of the pharmacy benefit in this year's *Drug Trend Report*, we have also broadened our services to make prescription drug use safer and more affordable.

Sincerely,

*Barrett A. Toan*

Barrett A. Toan  
Chairman and Chief Executive Officer

*Introduction*

DRUGTREND  
2002 *Report*

## Introduction

### Background

The year 2002 was a year characterized by national concern over homeland security, the war on terrorism, potential war with Iraq, a sluggish economy, and federal and state surpluses that turned into substantial deficits. In the public sector, the addition of a Medicare prescription drug benefit died over philosophical and partisan differences. Proposals for a Medicare prescription drug benefit have reappeared, but they are embroiled in debates over comprehensive Medicare reform. In addition, they must somehow be financed as budget deficits continue to grow. Unlike the federal government, states are required to have balanced budgets. In 2002, most states experienced severe budget problems that continue into 2003 and likely into 2004. As a consequence, many states have been forced to reduce spending for Medicaid, the federal/state program that provides medical care for the poor. Budget problems were not limited to the public sector, however. The economic downturn hit the private sector hard, resulting in large layoffs and subsequent rises in unemployment rates, as well as in a growing inability of employers to pay for the rapid growth in healthcare premiums.

As economic problems hurt the public and private sectors, healthcare costs increased substantially. After stabilizing at between 5 percent and 6 percent between 1994 and 1998, the annual growth rate in total national health expenditures has inched up, reaching \$1.4 trillion, or \$5,035 per capita, in 2001 — 8.7 percent above 2000 levels<sup>1</sup> (see Figure 1). National health expenditures for prescription drugs grew at an even more sizeable annual rate, peaking at 19.7 percent in 1999 before ebbing to still significant annual growth rates of 16.4 percent and 15.7 percent in 2000 and 2001, respectively. These rates of increase were higher than any of the other major components of national health expenditures.

In contrast, the annual growth rate in national expenditures for hospital care and physician and clinical services rose over the last several years — particularly in 2001 — after declining in the early and mid-1990s. The annual growth of expenditures for hospital care actually declined from 10.1 percent in 1990 to 2.9 percent in 1998, before creeping back up to 8.3 percent in 2001. Annual growth rates in national spending for physician and clinical services declined from 11.2 percent in 1990 to 4 percent in 1996 before rising by 5 percent, 6.6 percent, 5.2 percent, 6.9 percent and 8.6 percent in the five succeeding years. As a proportion of overall national healthcare costs, prescription drugs rose from 5.8 percent in 1990 to 9.9 percent in 2001. Conversely, the percentage attributed to hospital care slowly declined from 36.5 percent in 1990 to 31.7 percent in 2001, while the proportion of total spending attributable to physician and clinical services remained stable at about 22 percent.

1. Adapted from: Centers for Medicare & Medicaid Services, Office of the Actuary: National Health Statistics Group; U.S. Department of Commerce, Bureau of Economic Analysis; and U.S. Bureau of the Census, Table 1: National Health Expenditures Aggregate and Per-Capita Amounts, Percent Distribution, and Average Annual Percent Growth, by Source of Funds, Selected Calendar Years 1990-2001 and Table 2: National Health Expenditures Aggregate Amounts and Average Annual Percent Change, by Types of Expenditure, Selected Calendar Years 1990-2001. Available at: <http://www.cms.hhs.gov/statistics/nhe/historicaltables.pdf>. Accessed January 29, 2003.

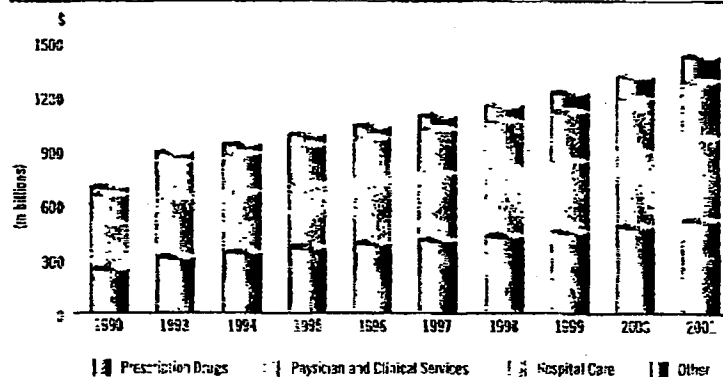
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Figure 1

National Health Expenditures for Selected Healthcare Accounts 1990 and 1993-2001



Source: Centers for Medicare &amp; Medicaid Services, Office of the Actuary, National Health Statistics Group.

Table 2: National Health Expenditures: Aggregate Amounts and Average Annual Percent Change, by Types of Expenditure: Selected Calendar Years 1990-2001. Available at: <http://www.cms.hhs.gov/statistics/nhe/historicaltables.pdf>. Accessed January 30, 2003.

Although spending for prescription drugs has grown at a dramatic rate, the absolute dollar amount expended on prescription medicines is substantially below what is spent on hospital care and physician and clinical services. By 2001, per capita prescription expenditures totaled \$497. By comparison, per capita spending for prescription drugs was less than one-third of what was expended for hospital care (\$1,594) and less than one-half of the expenditure for physician and clinical services (\$1,108).<sup>1</sup> Consequently, even though the percentage growth in per capita spending for prescription drugs between 2000 and 2001 was far higher than for hospital care and physician and clinical care, the absolute annual dollar increases for hospital care (\$106) and physician and clinical care (\$77) were larger than for prescription drugs (\$63).<sup>2</sup>

The Office of the Actuary for the Centers for Medicare and Medicaid Services (CMS) projects that national health expenditures will grow by 8.6 percent in 2002, then gradually decline to an annual 6.9 percent growth rate in 2009 and remain at about that level through 2012. Expenditures for prescription drugs are predicted to grow by 14.3 percent in 2002, with the annual rate of growth declining to 9.5 percent from 2009 through 2012. As a result, the proportion of total national health expenditures accounted for by prescription drugs is projected to grow from 9.9 percent in 2001 to 14.5 percent in 2012.<sup>3</sup>

2. Leff, K. Smith C. Cowan C. Lazerty H. Sosenig A. Collin A. Trends in U.S. health care spending, 2001. *Health Affairs*. 22(3):22(1):154-164.

3. Ibid.

4. Centers for Medicare and Medicaid Services, Office of the Actuary, and the U.S. Department of Commerce, Bureau of Economic Analysis and Bureau of the Census, as cited in: Mettler S. Smith S. Keshan S. Clemens M. Von G. Zezza M. Health care spending projections for 2002-2012. *Health Affairs-Web Exclusive*. No Date Given. Available at: <http://www.healthaffairs.org/WebExclusives/2202-reflex.pdf>. Accessed January 2003.

The impact of rising health costs has been felt by state Medicaid agencies, as well as by private employers. In terms of the former, total Medicaid costs grew by 13.4 percent in 2002, on top of the 11 percent growth experienced in 2001. They are expected to grow by about another 9 percent in 2003.<sup>5</sup> Prescription drug costs have been a major driver of these increases. Indeed, between 1998 and 2000, annual Medicaid prescription drug costs grew by around 20 percent and increased by over 28 percent in 2001.<sup>6</sup> While the increasing number of Medicaid recipients has contributed to this growth, the ascension of drug costs is explained only partially by this phenomenon. (See Appendix B for a more detailed explanation of Medicaid prescription cost trends.) In terms of the latter, private health benefit premiums have risen substantially over the last several years, and that increase is projected to continue into 2003. A Buck Consultants survey of health insurers found that health premiums grew between 13 percent and 14.9 percent in 2002. Depending on the product, the rate of growth was projected to continue at about those same levels in 2003. The trend for prescription drug card programs was 18.4 percent in 2002, and it is projected to be 16.9 percent in the first half of 2003.<sup>7</sup> The 2003 Segal Company Cost Trend Survey reported that 2003 medical plan costs, including prescription drugs, will rise between 14.4 percent and 16.2 percent, depending on plan type. Prescription drug carve-out plans are anticipated to grow by 19.5 percent in 2003 for those under 65 years old and by 19 percent for those 65 and older.<sup>8</sup> A poll conducted by Mercer Human Resource Consulting found that healthcare premiums will increase by 14 percent in 2003 after growing by 14.7 percent in 2002. Together, these growth rates represented the largest two-year increase since 1990.<sup>9</sup> Finally, Hewitt Associates reported that companies are anticipating a 15 percent rise in health premiums in 2003<sup>10</sup> while Towers Perrin reports expected increases of 16 percent.<sup>11</sup>

The figures cited above clearly demonstrate the magnitude of the financial burden that plan sponsors must bear for health benefit costs. Stories abound in the media regarding the negative effects that rising health premiums have on companies and on employees and their families. According to Hewitt, "The majority (94 percent) of participating companies also report that their CEO, CFO and CHRO are significantly or critically concerned about the rising costs of health benefits and the impact on corporate costs, while exactly 90 percent are significantly or critically concerned about their impact on employees."<sup>12</sup> Larger employers reduced the number of HMO plans they

5. Smith V, Ellis E, Gifford K, Ramesh R, Vaccaro V. Medicaid spending growth: a 50-state update for fiscal year 2003. Kaiser Commission on Medicaid and the Uninsured. January 2003. Available at: <http://www.kff.org/document/2003/20030113/4682.cdf>. Accessed January 14, 2003.
6. Adapted from: Medicaid Statistical Information System (MSIS) and HCFA-2262 State tables. Available at: <http://ems.hhs.gov/medicaid/csis-msis.asp>. Accessed September 24 and 27, 2002, and October 2 and 16, 2002.
7. Health care costs continue to rise, according to survey by Buck Consultants [press release]. New York: Buck Consultants; August 8, 2002. Available at: <http://www.buckconsultants.com/content/pr293.html>. Accessed March 25, 2003.
8. 2003 Segal Health Plan Cost Trend Survey [abstract]. November 2002. Available at: <http://www.segalco.com/corporate/pub-corporate.cfm?id=415>. Accessed February 2, 2003.
9. Rate hikes pushed employers to drop health plans, cut benefits in 2002-but average cost still rose 14.7% [press release]. New York: Mercer Human Resource Consulting; December 9, 2002.
10. Employers concerned about the impact of rising health care costs and are evaluating alternatives [press release]. Lincolnshire, Illinois: Hewitt News and Information; January 14, 2003.
11. Enochs, L. Employment: rising health care costs impact hiring rates. *The Seattle Times*. February 13, 2003. Available at: <http://archives.seattletimes.nwsource.com/cgi-bin/xis.cgi/web/vortex/display?slug=bizhealthcosts13&date=20030213&query=health+care+Enochs>. Accessed February 14, 2003.
12. Employers concerned about the impact of rising health care costs and are evaluating alternatives [press release]. Lincolnshire, Illinois: Hewitt News and Information; January 14, 2003.

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offered and used this added leverage, in conjunction with plan design changes, to curb HMO growth to 8.1 percent. In contrast, smaller employers, with no buying leverage, saw HMO premiums jump by 25.9 percent in 2002. Faced with such substantial increases in healthcare costs, the percentage of smaller employers — those with between 10 and 50 employees — that offered a health plan dropped from 66 percent to 62 percent.<sup>13</sup> Some companies that have declared bankruptcy have eliminated health benefits for retirees.<sup>14</sup> Most plan sponsors have and/or will raise members' financial responsibility for healthcare costs through higher member copayments/deductibles or premium contributions. Some momentum is also building toward more consumer-driven approaches, such as tiered copayments for networks, drugs and consumer-directed health plans.<sup>15</sup> In a sign that employees are becoming increasingly concerned about their health benefits, General Electric Company's union workers threatened to strike over rises in healthcare copayments.<sup>16</sup>

While the overall picture of rising health and pharmacy costs appears bleak, the prescription drug side of the equation includes a couple of positive dynamics that may moderate the magnitude of future cost increases. First, several heavily used brand products — Prozac<sup>®</sup>, Glucophage<sup>®</sup>, Zestril<sup>®</sup>/Prinivil<sup>®</sup>, Zestoretic<sup>®</sup>/Prinzide<sup>®</sup> and Prilosec<sup>®</sup> — have lost patent protection, allowing generic versions to enter the market in the past 18 months. Prozac<sup>®</sup>, an antidepressant, went generic in August 2001 and within 12 weeks, about three-fourths of Prozac<sup>®</sup> prescriptions for Express Scripts members were converted to the generic (fluoxetine). The generic conversion rate (the proportion of multi-source brand prescriptions that have been filled by generics) for Prozac<sup>®</sup> has stabilized at about 94 percent. In 2002 the combined market share for Prozac<sup>®</sup> and fluoxetine actually declined from 14.8 percent in January to 13 percent in December. When the oral antidiabetic agent Glucophage<sup>®</sup> went generic in late January 2002, it experienced a rapid conversion from the brand to the generic product (metformin). Within 2 months, over 80 percent of branded Glucophage<sup>®</sup> was converted to metformin and over 90 percent within 6 months. The combined market share of Glucophage<sup>®</sup> and metformin declined slightly (1.4 percentage points) during 2002 (see Figure 2). The conversion of brand Zestril<sup>®</sup>/Prinivil<sup>®</sup> and Zestoretic<sup>®</sup>/Prinzide<sup>®</sup> to their respective generic equivalents was even faster, reaching 85 percent in 2 months and 90 percent in 4 months. Despite the relative therapeutic equivalency of other brand products in this therapeutic class, the combined market share of Zestril<sup>®</sup>/Prinivil<sup>®</sup> and Zestoretic<sup>®</sup>/Prinzide<sup>®</sup> and their respective generic equivalents remained flat at about 29 percent (see Figure 3).

13 Rate hikes pushed employers to drop health plans, cut benefits in 2002-but average cost still rose 14.7% (press release). New York: Mercer Human Resource Consulting, December 5, 2002.

14 Canuso D. Sear economy, corporate scandals put retirees' health benefits in peril. *St. Louis Post Dispatch*, February 15, 2003.

15 Kaiser Family Foundation, National survey of small businesses, April 2002. Available at: <http://www.kff.org/content/2002/2/020402a/>. Accessed January 2003.

16 Rate hikes pushed employers to drop health plans, cut benefits in 2002-but average cost still rose 14.7% (press release). New York: Mercer Human Resource Consulting, December 5, 2002.

17 G.E. workers set to strike over insurance. *Bloomberg News*, December 31, 2002. Available at: <http://www.bloomberg.com/news/index.php?NewsID=145>. Accessed January 2003.

Figure 2  
2002 Generic Conversion Rates for Glucophage® to Metformin and Market Share for Glucophage® and Metformin

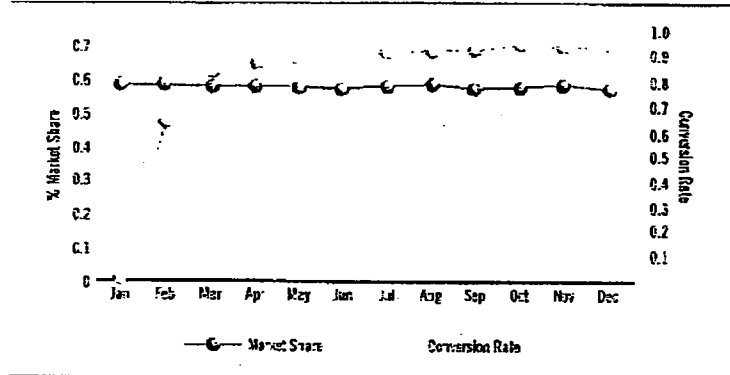


Figure 3  
2002 Generic Conversion Rates for Zestril®/Prinivil® to Lisinopril and Prinzip®/Zestoretic® to Lisinopril/HCTZ and Market Share for Zestril®/Prinivil®, Prinzip®/Zestoretic®, Lisinopril and Lisinopril/HCTZ

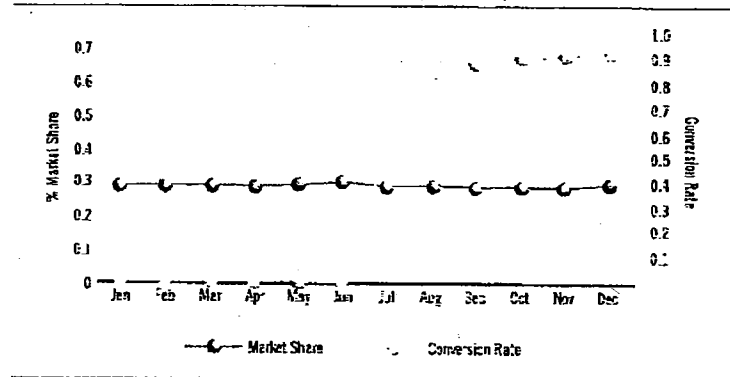
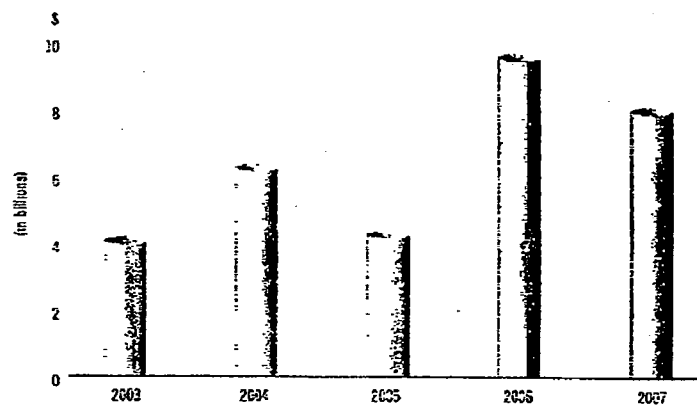


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A significant number of additional brands will lose their respective patents in the next several years. Indeed, as is shown in Figure 4, \$32.3 billion worth of brand patents will expire over the next 5 years. These products represent 16.8 percent of U.S. prescription drug sales in 2002.<sup>18</sup> The impact on prescription drug costs, and consequently on trend, will be considerable. In 2002, the use of generic products instead of their branded counterparts reduced trend by 2.1 percent, or \$12.70 Per Member Per Year (PMPY). The generic fill rate, which grew from 41.5 percent in the fourth quarter of 2001 to 45.9 percent in the fourth quarter of 2002, is projected to increase to 53.1 percent by the fourth quarter of 2007<sup>19</sup> (see Figure 5). Those percentages could increase even more, as would the reduction in trend, if the use of generic products went beyond mere substitution for their brand product counterparts and extended to utilization, when appropriate for a given patient, instead of other therapeutically equivalent brand products.

Figure 4

U.S. Sales for Brand Products with Patent Expirations Between 2003 and 2007

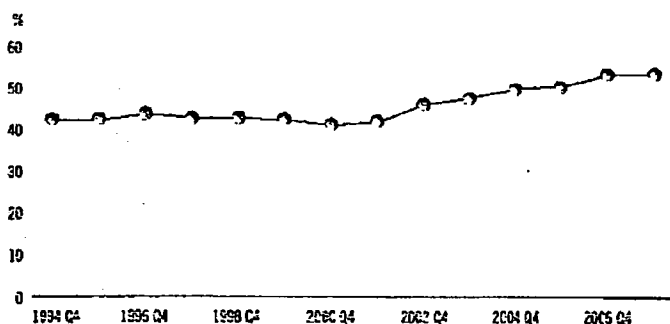


Adapted from: JP Morgan Securities, Inc. Industry update, *Prescription Paid* February 14, 2003, and *Markets W. Top 200 brand and generic drugs by retail sales*, *Drug Topics*, 2002:4:31 Available at: <http://dl.pdf.research.com/content/journals/d/data/2002/0218/d01cp2000ns02b.html>. Accessed February 16, 2003.

<sup>18</sup> Adapted from: IMS reports 12.8 percent dollar growth in 2002 U.S. prescription sales. (press release) Plymouth Meeting, Pennsylvania: IMS Health; February 21, 2003. Available at: <http://www.imshealth.com>. Accessed February 21, 2003.

<sup>19</sup> Express Scripts data and projections.

Figure 5  
Generic Fill Rate Fourth Quarter 1994 to Fourth Quarter 2007 (Estimated)



Source: Express Scripts data and projections.

A second noteworthy event in 2002 was the introduction of prescription strength Claritin® (loratadine) to the over-the-counter (OTC) market. In the past, most OTC products were lower in strength than the prescription version of those products. In the case of Claritin®, however, the prescription strengths went OTC and the prescription versions were removed from the market. This action is consistent with current FDA regulations, which state that a drug product cannot exist as both a prescription and an OTC product in the same strength and for the same uses. Moreover, OTC Claritin was not brought to market until December 2002. Most plan sponsors had little or no time to determine whether to cover only OTC Claritin® (and now other OTC versions of loratadine) in 2003, and/or to cover some or all of the prescription non- and low-sedating brand antihistamine products and, if so, at what copayment levels. Nonetheless, the OTC availability of non-sedating antihistamine products represents a previously unavailable avenue for plan sponsors to use in reducing prescription drug costs by changing drug coverage rules and/or attaching high copayments to the prescription products.

Prilosec® potentially represents a hybrid opportunity for capitalizing on generic and OTC products to reduce costs — but with important caveats. First, as a result of a court decision, generic Prilosec® (omeprazole) in both the 10mg and 20mg strengths can be manufactured by only one company, and that exclusive right could last for months, if not years. This situation is unusual because the first generic manufacturer generally is granted exclusive marketing rights for only the first 6 months of generic availability. Therefore, the price of a newly-introduced generic product is typically higher than its price after the first 6 months when competitive pressures from multiple manufacturers drive down the price. Because of the extended exclusivity attached to omeprazole, its initial relatively high price could extend for up to 5 years until additional manufacturers can also bring omeprazole to market. Thus, when brand rebates are taken into account, the price difference between generic omeprazole and branded proton pump inhibitor (PPI) products is much less than usual. Moreover, even in the short run, the use of omeprazole has been curtailed by an insufficient supply of the product.

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A second reason that the Prilosec®/omeprazole situation is unique relates to its OTC status. When labeling issues are finalized, the Food and Drug Administration (FDA) will grant the 20mg strength of Prilosec® OTC status, but only with a recommendation that its use be limited to 14 days, based on clinical reasons. Prescription Prilosec® has several long-term indications. The short-term use guidance for the OTC version puts plan sponsors in a difficult position when deciding whether to cover OTC Prilosec®, but not similar prescription proton pump inhibitors; to cover only the OTC product; to cover the OTC product at a relatively low copayment while covering prescription products at a substantial copayment; or to cover prescription PPIs only and forego the OTC opportunity.

Against this backdrop, prescription drug costs continue to increase substantially, and they are projected to grow at double digit rates for the foreseeable future. However, there are opportunities to reduce the rate of such increases, primarily through promoting the use of generic and lower cost brand products. The magnitude of trend increases in the future will reflect the degree to which plan sponsors are willing to adopt plan design strategies that encourage the use of these lower cost products.

### Summary Of Findings

In 1997, Express Scripts published the first edition of the *Drug Trend Report* covering the 1993-1996 time period. The intent of the *Drug Trend Report* series is to provide our clients with a better understanding of the dynamics underlying both current drug cost increases and future drug cost trends. This seventh edition of Express Scripts' *Drug Trend Report* discusses the magnitude of and the reasons for prescription drug cost increases between 2001 and 2002. Among the key findings of this study are:

#### Between 2001 and 2002

- PMPY ingredient costs grew by \$91.40, or 18.5 percent in 2002.
- The rise in per prescription costs accounted for 60.5 percent of this overall increase; 34.2 percent is attributable to increased utilization and 5.3 percent to the introduction of new drugs.
- The inflation rate for common drugs (drugs available in 2001 and 2002) grew by 7.5 percent — the fifth consecutive year that inflation topped 5 percent and the highest rate seen since the *Drug Trend Report* was initiated. Inflation accounted for 43.4 percent of the overall 2001-2002 drug expenditure increase.
- The use of generics instead of their respective brand counterparts reduced the PMPY ingredient cost increase by 2.1 percent.
- Slightly more of the utilization increase was due to more members using prescription drugs than to more prescriptions per utilizer.
- Ten drug classes accounted for 53.9 percent of the total 2002 PMPY ingredient cost.

- Higher costs of gastrointestinal, antihyperlipidemic, antidepressant and antihypertensive medicines accounted for \$33.30, or 36.4 percent, of the total \$91.40 PMPY ingredient cost increase in 2002.
- Five percent of members accounted for 50.7 percent of total 2002 PMPY ingredient cost and 10 percent of members for 69.7 percent of ingredient cost.

#### 2003 Through 2007 Projections

PMPY ingredient costs are projected to increase by:

- 15.5 percent in 2003
- 16.0 percent in 2004
- 16.0 percent in 2005
- 15.6 percent in 2006
- 15.2 percent in 2007

These trend figures reflect past experience with and future expectations about the magnitude of drug cost increases on an ingredient cost basis. When considered from a net cost perspective — costs after member financial contribution and manufacturer rebates — plan sponsors can significantly curb costs. Plan sponsors that took aggressive steps saw their drug cost trend actually decrease by as much as 20 percent, with the average PMPY net claim cost increase being between 6 percent and 11 percent.

The key cost drivers that underlie the 2001–2002 drug cost growth are discussed in the first section of this Report. Express Scripts' forecast of PMPY ingredient costs for the period from 2003–2007 is then presented, along with a discussion of the new drug pipeline anticipated during this period. Also included in the forecast section is an analysis of the key products that are scheduled to lose patent protection between 2003 and 2007. A new chapter this year focuses on specialty injectable pharmacy products and the growing role these drugs have in the overall drug treatment arsenal. The concluding portion of this Report discusses the types of actions that plan sponsors can take to offset growing prescription costs. Appendix A includes an analysis of drug cost changes within the most costly therapy classes between 1998 and 2002. Also highlighted are some of the key changes in utilization of specific drugs and drug classes, as well as factors that are likely to impact future product mix in these classes. Appendix B is a new addition to the *Drug Trend Report*. This appendix provides an overview of the Medicaid program and an analysis of the prescription drug trend for Medicaid recipients from 1996 through 2001, the latest year for which data were available at the time this Report was written.

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### Methods

The analyses contained in the 2002 *Drug Trend Report* are based on prescription medications for a sample of Express Scripts commercial clients that maintain individual member eligibility data and use Express Scripts for both retail and mail pharmacy services. Medicaid recipients and Medicare beneficiaries receiving drug coverage through Medicare Plus Choice plans are excluded from this study because of their unique demographics and drug coverage policies. About two-thirds of the resulting 2002 sample consists of non-managed care commercial members, and about one-third is managed care commercial members.

Cost data included in past Reports were expressed on an Average Wholesale Price (AWP) ingredient cost (retail "list" price of the medication) basis. Thus, retail network discounts, mail discounts, dispensing fees, rebates and member financial contributions were not reflected in these data. This approach was adopted to ensure comparability across time periods and across client groups; however, it does not take into account that retail and mail discounts on generic products are on average about three times greater than on single-source branded products. This differential did not have a material impact on the trend percentage in past Reports because the generic fill rate was relatively stable during that period. Beginning in 2001 and extending over the next several years, however, the number of single-source brand medicines losing patent protection is growing substantially. Correspondingly, generic fill rates are increasing, reaching 45.9 percent in the fourth quarter of 2002. To take this phenomenon into account, ingredient costs were computed using a standard discount of 12 percent for brand products and 36 percent for generic products off of the AWP cost per unit, rather than computing ingredient costs on an AWP basis. Ingredient costs going back to 1998 were also re-stated using the same discount percentages to maintain comparability in the trend figures over time. When comparing these two ingredient cost calculation methodologies, the annual percentage trend figures do not vary more than 0.2 percent between 1998 and 2001. However, the brand/generic and therapeutic mix components are somewhat different because of this change in methodology. The 12 percent and 36 percent discount figures used are not meant to represent actual client discounts. Rather, they were selected primarily to reflect the roughly three to one ratio between the magnitude of brand and generic discounts that apply to the Express Scripts' book of business. Also, it should be noted that generic discount rates can vary significantly across specific products.

As was the case in previous Reports, prescriptions counts have been converted to equivalent numbers that would have been dispensed through retail pharmacies to adjust for differential mail usage rates and varying benefit structures across Express Scripts clients. Drugs sold over-the-counter and prescriptions dispensed in inpatient settings are not included in this analysis. Finally, overall figures may not represent actual client experience due to differences in plan design.

The 2002 sample consists of 3 million unique members. To prevent significant distortion in the sample, membership from any given client was limited to no more than 5 percent of the overall sample. The average age of the 2002 sample was 35, compared to the average age of 34.3 for the 2001 sample.

*Trends in  
Expenditures*

DRUG TRENDS

2002 *Report*

## Trends in Expenditures for Prescription Drugs

After growing by 16.7 percent in 2001, PMPY ingredient costs rose 18.5 percent to \$585.60 in 2002. As was the case in 2001, PMPY cost increases were higher for managed care clients (20.3 percent) than for other clients (17.1 percent). In 2001, however, mix and number of units per prescription accounted for the difference. The 2002 disparity was caused by the 9.2 percent utilization increase among managed care clients versus 4.7 percent for other clients. The actual net claim cost trend for Express Scripts clients ranged from a 20 percent decrease to a 35 percent increase, depending on how aggressively plan sponsors chose to implement Express Scripts' recommended cost-management programs.

The 2001-2002 PMPY ingredient cost trend was analyzed in terms of the following three dimensions:

1. Changes in the utilization of "common drugs" (medications that were available for use in 2001 and 2002)
2. Increases in ingredient costs per prescription of these common drugs
3. Introduction of "new products" to the market (drugs available for use in 2002 but not in 2001)

Utilization of common drugs was divided into two components: prevalence and intensity. Prevalence tracks the proportion of members who use one or more prescription drugs from one year to the next. Intensity is the number of prescriptions per person from one year to the next. Per prescription costs were decomposed into the relative effects of inflation, units per prescription, brand/generic mix and therapeutic mix. The impact of new drugs was divided into the independent contributions of change in per prescription cost (the differential between the cost of new drugs and the average cost of common drugs) and the added costs associated with increased utilization of new drugs (see Table 1).

Table 1  
Components of Per Member Per Year Cost Trend 1997-2002\*

	1997 v 1998	1998 v 1999	1999 v 2000	2000 v 2001	2001 v 2002
Inflation	5.1%	5.4%	5.4%	5.6%	7.5%
x Units per Rx	0.6%	0.2%	1.0%	0.1%	-0.1%
x Brand/Generic Mix				-1.4%	-2.3%
x Therapeutic Mix	5.0%	3.1%	5.1%	4.4%	5.3%
x Utilization	3.9%	6.2%	2.7%	5.3%	6.5%
= Common Drug	15.2%	15.6%	15.9%	15.6%	17.5%
+ New Drugs	1.6%	1.8%	0.3%	1.0%	1.0%

\* The percentage contribution of each factor does not total to the All Drug percentage increase. The calculation takes the base cost for a given year and multiplies it by one times the percentage contributed by the first factor (inflation). The resulting total is then multiplied by the percentage contributed by the second factor (number of units dispensed), and so on for each Common Drug factor. The percentage contribution of the New Drugs is then added to the total Common Drug percentage to yield an All Drug percentage increase. The final results may differ due to rounding.

The following sections discuss the degree to which each of these cost-trend components influenced cost increases for the combined non-managed and managed commercial memberships between 2001 and 2002.

### Changes in Common Drug Costs Between 2001 and 2002

#### *Utilization of Common Drugs*

To ascertain the variable use patterns across therapeutic drug groupings, common drugs were categorized into therapy classes — groups of pharmaceutical agents that are chemically or therapeutically related. Products were grouped according to the first two digits of the 14-digit Generic Product Identifier (GPI) code as classified by Facts and Comparisons. This classification system defines broad drug groups used to treat similar medical conditions.

The change in overall utilization of common drugs was analyzed in terms of the relative contributions from intensity of use and prevalence of use to overall utilization. Intensity of use is calculated as the number of prescriptions divided by the number of utilizer member months, both in the aggregate and by therapy class. Prevalence is also measured on an aggregate level as well as on a therapy class basis. The change in aggregate prevalence is measured by the increase or decrease in the percentage of members who use any prescription drug in any therapy class. Change in prevalence at the therapeutic class level is measured by the change in the proportion of members who use a drug in a given therapy class. A change in the prevalence rate in a given therapy class does not necessarily translate into a change in the aggregate (all drug) prevalence rate. Members who used drugs in the specific therapy class in 2002 could have counted as a drug utilizer in 2001 due to their use of drugs in other therapy classes in 2001. For both of these measures, prevalence is calculated as the ratio of the total number of member months for all utilizers divided by the total number of member months for all members in the sample.

Common drug utilization grew by 6.3 percent from 10.59 PMPY in 2001 to 11.26 in 2002, accounting for almost one-third of the overall PMPY 2001-2002 cost growth. The level of growth, the same seen between 2000 and 2001, is similar to the level experienced in the 1998-1999 period. A slightly higher proportion of the aggregate utilization trend is attributable to increased intensity, 3.3 percent compared to prevalence which rose by 3 percent. The prevalence rate grew from 62.9 prescriptions per 100 members in 2001 to 64.8 per 100 members in 2002. Intensity increased from 1.4 prescriptions per utilizer to 1.5 per utilizer.

Wide variations were seen in the magnitude and direction of changes in utilization of common drugs between 2001 and 2002, as is true every year (see Table 2). Utilization of common drugs grew in 20 of the top 25 therapy classes in 2002. Moreover, increased utilization in the top six classes in terms of utilization — antihypertensives, antidepressants, antihyperlipidemics, gastrointestinal, narcotic analgesics and antidiabetics — accounted for almost three-fourths of the total increase in common drug utilization.

Changes in the use of cardiac-related drug classes varied significantly in 2002. The antihypertensive therapy class consists mainly of angiotensin converting enzyme inhibitors (ACEIs), angiotensin receptor blockers (ARBs), vasodilators and combination products. This class continued to be the most widely prescribed therapy class at 0.86 prescriptions PMPY in 2002. The 10.6 percent increase in the use of these products reflects a steady annual increase in utilization seen over the last several years. The aging of the population and aggressive treatment of hypertension likely stimulated this strong growth pattern. As a consequence, the prevalence rate for these drugs grew by 9.7 percent to 8.7 per 100 members, while intensity remained basically flat at 0.82 prescriptions per utilizer. ACEIs continue to be the most widely used antihypertensive products because of the perception that they have superior efficacy and better side effect profiles. Although they went generic in July 2002, the combined market share of Zestril®/Prinivil® and their generic changed little after July.

The use of beta blockers and diuretics, the recommended first-line agents for uncomplicated hypertension, grew by 9.2 percent and 3.3 percent, respectively. The combined increased use of antihypertensives, beta blockers and diuretics accounted for almost one-quarter of the overall growth in common drug utilization. In contrast, the use of calcium blockers continued to decline, dropping by 1.5 percent as prevalence decreased by 1.9 percent. A recent study suggested that diuretics were more effective than ACEIs and calcium blockers as first-line treatment of hypertension.<sup>20</sup> Subsequent research reported that patients using ACEIs were less likely to die of heart disease than those taking diuretics.<sup>21</sup> Both studies may hasten the decline in the use of calcium blockers in hypertension.

Utilization of antihyperlipidemics, the third most widely used class, once again increased substantially in 2002, rising by 13 percent to 0.65 prescriptions PMPY. About 85 percent of the increase is attributable to the growing number of people who take these medications: prevalence rates for this class grew by 11 percent to 7.3 per 100 members. The dramatic increases in the use of antihyperlipidemics have been spurred by evidence that their use reduces mortality, by new guidelines that increase the total number of patients eligible for treatment and by extensive Direct-to-Consumer (DTC) advertising (\$209 million from November 2001 through October 2002).<sup>22</sup> The market share for Lipitor® grew from 54.7 percent to 55.4 percent, while Zocor® and Pravachol® maintained their market shares at about 15.6 percent and 12.5 percent, respectively.

20. Cushman WC, Ford CE, Cutler A, et al. Success and predictors of blood pressure control in diverse North American settings: the Antihypertensive and Lipid-lowering Treatment to Prevent Heart Attack Trial (ALLHAT). *Journal of Clinical Hypertension* (Greenwich). 2002;4(6):393-405.

21. Nelson MR, Reid CM, Krum H, Ryan P, Wang LM, McNeill JJ. Short-term predictors of maintenance of normotension after withdrawal of antihypertensive drugs in the second Australian National Blood Pressure Study (ANBP2). *American Journal of Hypertension*. 2003;16(1):35-45.

22. CMR, as cited in: JP Morgan Securities, Inc. *Prescription Pad*, January 16, 2003.

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Table 2  
Utilization of Common Drugs for the Top 25 Therapy Classes 2001-2002  
Ranked by 2002 PMPY Prescriptions

RANK	THERAPY CLASS	2001 Rx PMPY	PREVALENCE % CHANGE	INTENSITY % CHANGE	2002 Rx PMPY	TOTAL % CHANGE
1.	Antihypertensives	0.77	9.7%	9.6%	0.86	10.5%
2.	Antidepressants	0.62	10.7%	4.4%	0.72	15.6%
3.	Antyperlipidemics	0.57	11.5%	1.8%	0.65	13.3%
4.	Gastrointestinals	0.44	9.5%	5.3%	0.50	15.3%
5.	Narcotic Analgesics	0.42	6.3%	3.1%	0.46	9.5%
6.	Antidiabetics	0.40	8.2%	0.9%	0.44	9.2%
7.	Estrogens	0.50	-4.9%	-7.0%	0.44	-11.5%
8.	Beta Blockers	0.39	9.1%	1.1%	0.43	9.2%
9.	Oral Contraceptives	0.34	11.6%	4.3%	0.40	16.3%
10.	Anti-rheum (NSAIDs)	0.39	-4.6%	4.4%	0.38	-0.4%
11.	Diuretics	0.36	2.5%	0.2%	0.38	5.3%
12.	Antiasthmatics	0.36	3.5%	-0.8%	0.37	2.5%
13.	Thyroid	0.35	4.6%	1.0%	0.35	0.6%
14.	Acidostimulants	0.33	-7.7%	9.3%	0.33	1.0%
15.	Cough/Cold	0.31	6.1%	1.1%	0.32	1.2%
16.	Calcium Blockers	0.32	-1.8%	0.3%	0.32	-1.5%
17.	Dermatologicals	0.31	-3.5%	3.0%	0.30	-3.7%
18.	Penicillins	0.30	1.6%	-1.1%	0.30	0.5%
19.	Antianxiety Agents	0.20	3.4%	1.6%	0.21	5.0%
20.	Macrolides	0.18	1.1%	-0.8%	0.18	0.4%
21.	Anticonvulsants	0.15	14.1%	0.4%	0.17	14.6%
22.	Misc. Endocrine	0.13	17.0%	3.5%	0.15	21.1%
23.	Decongestants	0.15	-2.6%	6.6%	0.15	3.8%
24.	Ophthalmic Products	0.15	-0.1%	1.1%	0.15	0.9%
25.	Cephalosporins	0.13	-1.2%	-0.6%	0.13	-1.8%
	Top 25	8.57	4.1%	2.0%	9.10	6.2%
	Other	2.02	-2.5%	9.7%	2.17	6.9%

PMPY utilization of antidepressants grew even faster than in 2001, rising 15.6 percent in 2002 to 0.72 prescriptions PMPY. As the second most widely used therapy class, growth in antidepressant use contributed over 15 percent to the overall common drug utilization increase. About two-thirds of the rise in antidepressant use is attributable to the increased prevalence rate, 9.5 per 100 members, making it the seventh highest class in terms of prevalence. The wide use of antidepressants is partially due to a number of new indications for antidepressant use in conditions such as social anxiety disorder, premenstrual dysphoric disorder, post traumatic stress disorder and generalized anxiety disorder. This class continues to be dominated by selective serotonin reuptake inhibitors (SSRIs) such as Prozac<sup>®</sup>, fluoxetine (the generic version of Prozac<sup>®</sup>), Zoloft<sup>®</sup>, Paxil<sup>®</sup> and Celexa<sup>®</sup>, and by selective norepinephrine reuptake inhibitors (SNRIs) such as Effexor<sup>®</sup>.

The PMPY use of gastrointestinal (GI) drugs grew by 15.3 percent in 2002. The increased number of users of these drugs, 8.2 per 100 members, contributed about two-thirds to the overall use that rose to 0.5 prescriptions PMPY in 2002. DTC advertising for this class was \$255 million for the 12 months ending October 2002.<sup>23</sup> The market share of proton pump inhibitors (Prevacid<sup>®</sup>, Prilosec<sup>®</sup>, Nexium<sup>®</sup>, Protonix<sup>®</sup> and Aciphex<sup>®</sup>) increased from 69.6 percent in 2001 to 73.9 percent in 2002 at the expense of the less expensive generic H2 blockers.

<sup>23</sup> *ibid.*

Narcotic analgesics was the fifth most used therapy class. PMPY use of this class rose 9.6 percent to 0.46 prescriptions PMPY in 2002. This growth in use was due to both prevalence and intensity increases. The prevalence rate for these drugs rose by 6.3 percent to 14.1 per 100 members in 2002, while intensity increased by 3.1 percent. Neither increase is surprising given the growing reliance on these medications for treatment of patients with lower back pain, more patients being treated in outpatient settings and longer survival times for higher numbers of terminally ill patients.

The PMPY utilization of common drugs in the non-steroidal anti-inflammatory (NSAID) class actually declined marginally (-0.4 percent) in 2002 to 0.38 prescriptions PMPY after growing by only 4.9 percent in 2001. The major reason for this slight decline was that some utilization of products in this class was shifted to a new product, Bextra<sup>®</sup>. Even though Bextra<sup>®</sup> did not come to market until spring 2002, it still managed to capture 4.6 percent of the NSAID market. When Bextra<sup>®</sup> is included, NSAID utilization actually increased by 4.5 percent. Cyclooxygenase 2 inhibitors (COX-2s), Celebrex<sup>®</sup>, Bextra<sup>®</sup> and Vioxx<sup>®</sup>, continued to grow their combined market share from 41.7 percent in 2000 to 47.6 percent in 2001 to 50.6 percent in 2002.

Antidiabetic drugs, the sixth most used therapy class, experienced a 9.2 percent increase in utilization to 0.44 prescriptions PMPY in 2002. Unlike in 2001, when intensity rose more than prevalence, in 2002 the prevalence rate for antidiabetic drugs grew by 8.2 percent, whereas intensity grew by 0.9 percent. The continued rise is attributable to an increasingly obese population and the emphasis on aggressive management of diabetes, as well as to the availability of newer oral products.

Substantial changes took place in the 2002 PMPY utilization of common drugs in several drug classes pertaining to women's health. The use of oral contraceptives increased by 16.3 percent to 0.4 prescriptions PMPY. This was due mostly to the 11.6 percent increase in the prevalence rate, likely reflecting more coverage of oral contraceptives by plan sponsors. Estrogen use dropped from the fourth highest used therapy class in 2001 to the seventh ranked class in 2002. This dramatic shift reflects an 11.5 percent decline in estrogen use to 0.44 prescriptions PMPY in 2002. The declining use of these products includes drops in prevalence and intensity, and corresponds to the release of two studies that called into question the use of combination estrogen/progestin hormone replacement therapy (HRT). In large part because of the fallout from these studies, many women who were using HRT products, or who would have started taking those products, instead used miscellaneous endocrines. A study conducted by Express Scripts revealed that 36 percent of women in a sample of Express Scripts members stopped using HRT combination products, more than four times the discontinuation rate during the same period the preceding year. On the other hand, 57 percent continued using the HRT combination products. The remainder switched to other products. These data suggest that when the longer-term risk of using HRT combination products was better understood, large numbers of women and their physicians acted promptly to avoid HRT and reduce their risk. Although these studies found no adverse effects among users of estrogen alone, 22.6 percent of an Express Scripts member sample discontinued use of any estrogen product and did not switch to a combination HRT product or to another agent used to treat osteoporosis. This was more than double the discontinuation rate for the same period in the previous year.

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This changed behavior was manifest in the 21.1 percent increase in the use of miscellaneous endocrines — particularly the use of products used to treat and prevent osteoporosis, such as Fosamax<sup>®</sup>, Evista<sup>®</sup> and Actonel<sup>®</sup>, which had a combined 86.7 percent market share in 2002 compared to their 83.3 percent level in 2001. Other types of drugs in this class are growth hormones and fertility agents. This follows the 30.1 percent increase in miscellaneous endocrines in 2001, when much conjecture was circulating about possible long-term HRT side effects, but no strong scientific proof had yet been released. Thyroid use continued to grow in 2002, reaching 0.35 prescriptions PMPY. Most of this rise was due to the 4.6 percent increase in prevalence to 3.6 per 100 members.

Antiasthmatic drugs, the twelfth most used class, experienced a modest 2.6 percent increase in use to 0.37 prescriptions PMPY in 2002. This entire rise was attributable to increased numbers of utilizers, reflecting the central role that prescription drug therapy plays in asthma control. The use of controllers such as Singulair<sup>®</sup> and Advair Diskus<sup>®</sup> grew considerably, by 16.5 percent and 12.6 percent, respectively.

The use of common antihistamine products, consisting overwhelmingly of low- and non-sedating brand products, remained flat at 0.33 prescriptions PMPY in 2002. However, the utilization figure does not take into account the market entry of Clarinex<sup>®</sup> in 2002. When Clarinex<sup>®</sup> is included, PMPY utilization of antihistamines actually rose by 11.3 percent. In the 12 months ending in October 2002, \$329 million was spent on DTC advertising for this class.<sup>24</sup> In December 2002, Claritin<sup>®</sup> was marketed as an over-the-counter (OTC) product.

After declining in 2000 and 2001, the PMPY use of products in the cough/cold class rose by a marginal 1.2 percent in 2002. Yet, with a 0.32 prescriptions PMPY utilization rate, cough/cold products still ranked as the fifteenth most used category of drugs, with 13.8 per 100 members taking drugs in this class. Generics continue to dominate the class, increasing their collective market share from 51.6 percent in 2001 to 53.5 percent in 2002 at the expense of Claritin-D<sup>®</sup>, Allegra-D<sup>®</sup> and Zyrtec-D<sup>®</sup>. Utilization of decongestants, a class consisting primarily of nasal steroids used to alleviate allergy symptoms, increased by 3.8 percent to 0.15 prescriptions PMPY in 2002. Unlike 2001, the 2002 rise was due solely to the increased intensity of use, as the number of people using these products declined 2.6 percent. Flonase<sup>®</sup> and Nasonex<sup>®</sup> continued to dominate this class with a combined market share of 60.3 percent.

<sup>24</sup> Ibid.



The PMPY use of anticonvulsants grew by another 14.6 percent to 0.17 prescriptions PMPY in 2002 after increasing by 10.7 in 2001. Virtually all of this rise was due to growing numbers of utilizers of these products. This rise was fueled by wider use of Neurontin® as a pain control medication. The market share for Neurontin® grew from 22.5 percent in 2000 to 25.4 percent in 2001 to 26.3 percent in 2002. The market share for Topamax® rose from 4.6 percent to 7 percent. This drug is indicated for the treatment of epilepsy, but it is often used for migraine pain and it may be used for weight control.

PMPY utilization of the use of drugs in the macrolide antibiotic class was flat in 2002. Only a marginal 0.5 percent growth was evident in PMPY penicillin utilization, and a 1.8 percent decline was seen in the use of cephalosporins.

#### ***Ingredient Cost Per Prescription***

Between 2001 and 2002, 50.5 percent of the overall PMPY ingredient cost rise was due to growth in per prescription costs, virtually the same as was the case between 2000 and 2001.

Components of the trend in the cost per prescription for common drugs are:

- **Inflation** (changes in the unit price charged for brands and generics available in both 2001 and 2002)
- **Brand/Generic Mix** (changes in the mix of brands and generics due to greater market share penetration of existing generics or the introduction of new generics)
- **Therapeutic Mix** (changes in the mix of chemical entities within and across therapeutic classes, and the introduction of new dosage forms for existing chemical entities)
- **Units** (the number of units dispensed per prescription)

Inflation had by far the greatest impact on the average ingredient cost per prescription for common drugs between 2001 and 2002, followed by therapeutic mix, brand/generic mix and the number of units per prescription (see Figure 6 and Table 3). The relative contributions of these factors to the overall increase in the average prescription ingredient cost for common drugs, and their variable impacts across therapy classes, are described on the following pages.

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**Figure 5**  
**Percent Change in Ingredient Cost Per Prescription Due to Inflation, Therapeutic Mix, Brand/Generic Mix**  
**and Units 2001-2002**



### ***Inflation***

The calculation of inflation in this Report is based on Average Wholesale Price (AWP) that First DataBank reports for each unit of a given product. This AWP per unit for each drug was then discounted 12 percent for brand drugs and 36 percent for generics. The inflation rate in this Report represents the difference between the weighted average discounted AWP per unit in 2001 and the weighted average discounted AWP price per unit in 2002 for common drugs, holding constant market share and units per prescription. The resulting inflation rate was 7.5 percent in 2002, marking the fifth consecutive year that inflation topped 5 percent. Based on Consumer Price Index (CPI) statistics reported by the U.S. Department of Labor (which defines inflation somewhat differently than this analysis), the inflation rate for prescription drugs was 5.2 percent in 2002. This level contrasts with the 4.6 percent inflation rate experienced in overall medical care.<sup>25</sup>

Inflation contributed 71.8 percent to the overall increase in the cost per prescription in 2002. As has been true in the past, inflation rates vary widely across brands and generics as well as by therapy class. In 2002, inflation was 8.4 percent for brand drugs and 3.1 percent for generics. As shown in Table 3 and Table 4, price increases were evident in all of the top 25 therapy classes. These increases ranged from 3.6 percent for calcium blockers to 13.5 percent for cough/cold and cephalosporins.

<sup>25</sup> Bureau of Labor Statistics, U.S. Department of Labor, Consumer price index-all urban consumers (current series). Available at: <http://www.bls.gov/cpi/home.htm#overview>. Accessed February 20, 2003.

Table 3  
Price Changes Due to Inflation for the Top 25 Therapy Classes 2001-2002  
Ranked by Percent Change

RANK	THERAPY CLASS	PRICE % CHANGE BRAND PRODUCTS	PRICE % CHANGE GENERIC PRODUCTS	PRICE % CHANGE ALL PRODUCTS
1.	Cough/Cold	14.8%	7.7%	13.5%
2.	Cephalosporins	17.2%	5.6%	13.5%
3.	Estrogens	12.7%	3.6%	12.2%
4.	Antihistamines	11.5%	61.6%	11.8%
5.	Decongestants	11.0%	-60.9%	11.0%
6.	Ophthalmic Products	10.6%	3.4%	5.8%
7.	Thyroid	6.7%	18.8%	9.2%
8.	Anticonvulsants	9.8%	2.0%	8.9%
9.	Dermatologicals	10.5%	-2.2%	8.8%
10.	Gastrointestinals	9.6%	0.5%	8.7%
11.	Antihypertensives	9.1%	0.9%	7.6%
12.	Antiasthmatics	8.6%	2.1%	7.6%
13.	Antidepressants	7.4%	3.6%	7.0%
14.	Oral Contraceptives	7.5%	3.7%	6.9%
15.	Arterial Agents	6.7%	6.5%	6.6%
16.	Antidiabetics	6.7%	0.5%	6.2%
17.	Anti-Rheum (NSAIDs)	7.3%	1.2%	5.2%
18.	Antihyperlipidemics	6.3%	2.6%	6.2%
19.	Beta Blockers	6.3%	4.9%	5.9%
20.	Penicillins	5.5%	4.1%	5.3%
21.	Narcotic Analgesics	6.7%	1.5%	5.0%
22.	Diuretics	13.9%	2.0%	4.8%
23.	Misc. Endocrine	4.7%	0.5%	4.7%
24.	Macrolides	4.2%	-0.5%	4.2%
25.	Calcium Blockers	3.7%	3.4%	3.6%
	Top 25	8.5%	3.0%	7.5%
	Other	8.1%	3.1%	7.6%

In general, therapy classes consisting of drugs used to treat respiratory conditions (cough/cold products, antihistamines, decongestants and antiasthmatics) experienced the greatest inflation increases in 2002. Cough/cold products and antihistamines, both dominated by low- and non-sedating antihistamine products, had inflation increases greater than 11 percent. As shown in Table 4, the most commonly dispensed versions of Claritin® and Claritin-D® 24 Hour both had 21.1 percent increases in 2002. These increases came after the introduction of the lower price product Clarinex® in early 2002 and before the introduction of OTC versions and the withdrawal of prescription versions for both Claritin® and Claritin-D® 24 Hour in late 2002. The generic inflation within the antihistamine class was due to dramatic cost increases for the generic promethazine. Price increases by the generic manufacturers of this product averaged almost 180 percent. However, the relatively small market share of this product, less than 5 percent, resulted in little impact on the class as a whole.

Table 4  
Price Changes for the Top 50 Consumer Brand Drugs 2001-2002

Ranked by Number of Prescriptions

Product	Unit Price On 12/31/2001	Unit Price On 12/31/2002	Percent Change	# of Price Changes Between 12/31/2001 and 12/31/2002
1. LIPITOR® 10MG	2.93	2.31	13.5%	2
2. LIPITOR® 20MG	3.14	3.44	9.4%	2
3. PREVACID® 30MG	4.14	4.65	11.7%	2
4. ORTHO TRI-CYCLEN®	1.15	1.32	13.5%	2
5. ZITHROMAX® 250MG	5.57	7.33	50%	2
6. PROLOSEC® 20MG	4.30	4.61	7.3%	1
7. CELEBREX® 200MG	2.75	2.82	4.6%	1
8. ZYRTEC® 10MG	1.98	2.04	3.0%	2
9. PREMARIN® 0.525MG	0.76	0.89	17.5%	2
10. CLARITIN® 10MG	2.67	3.23	21.1%	3
11. FOSAMAX® 70MG	15.19	17.14	5.9%	1
12. VIOXX® 25MG	2.75	2.88	4.5%	1
13. ALLEGRA® 180MG	2.19	2.35	7.5%	2
14. PREMPRO® 0.625-2.5 MG	1.18	1.30	10.0%	2
15. A-BUTERG.® 96MG	1.25	1.26	0.0%	0
16. NORVASC® 5MG	1.41	1.45	3.0%	2
17. NEXIUM® 40MG	4.50	4.42	10.6%	2
18. FLONASE® 50MCG	3.61	4.06	12.7%	2
19. ZOLOFT® 100MG	2.49	2.52	1.4%	2
20. CELEXA® 20MG	2.25	2.41	7.3%	2
21. TOPROL XL® 50MG	0.65	0.74	12.9%	3
22. PAXIL® 20MG	2.72	2.82	4.0%	1
23. WELLBUTRIN SR® 150MG	1.69	1.92	13.8%	2
24. ZOLOFT® 50MG	2.42	2.52	4.3%	2
25. NORVASC® 10MG	2.17	2.17	0.0%	1
26. LIPITOR® 40MG	3.50	3.54	4.2%	2
27. GLECOMFAGE XR® 500MG	0.59	0.77	11.0%	1
28. PRAVACHOL® 40MG	4.14	4.35	5.0%	1
29. PROTONIX® 40MG	3.13	3.51	12.2%	3
30. SYNTHROID® 100MCG	0.39	0.42	6.7%	2
31. NASONEX® 50MCG	3.52	4.24	14.8%	4
32. PRAVACHOL® 20MG	2.55	2.89	13.4%	2
33. LEVAGUR® 500MG	8.88	10.08	13.5%	2
34. CLARINEX® 5MG	2.19	2.28	4.2%	1
35. TOPROL XL® 100MG	0.96	1.11	12.9%	3
36. ALLEGRA-D® 120-60MG	1.23	1.38	12.5%	2
37. CELEXA® 40MG	2.34	2.52	7.5%	2
38. CIPRO® 500MG	4.67	5.47	17.0%	2
39. DIFLUCAN® 150MG	12.29	13.14	7.0%	2
40. FLOMAX® 0.4MG	1.77	1.90	7.1%	2
41. EFFEXOR XR® 75MG	2.62	2.85	9.0%	2
42. ZESTRIL® 10MG	1.01	1.15	13.5%	2
43. ALLEGRA® 60MG	1.18	1.35	14.6%	2
44. CLARITIN-D 24 HOUR® 240-10MG	3.00	3.64	21.1%	3
45. AGMENTIN® 575-125MG	5.40	5.61	4.0%	1
46. ACCUPRIL® 20MG	1.05	1.15	9.4%	2
47. TREXID® 160MG	2.49	2.74	10.1%	3
48. SINGULAR® 10MG	2.75	2.51	5.9%	1
49. PREMARIN® 1.25MG	1.35	1.23	17.5%	2
50. SYNTHROID® 75MCG	0.58	0.41	6.7%	2

Decongestants also experienced double-digit inflation in 2002. The prices for the top two products in this class, Flonase<sup>®</sup> and Nasonex<sup>®</sup>, rose 12.7 percent and 14.8 percent, respectively. These two products accounted for over 60 percent of the utilization in this class and contributed significantly to the inflation trend. However, it must be noted that prices for all of the products that accounted for over 99 percent of the prescriptions in the class increased by more than 10 percent in 2002.

Antiasthmatics were led by price increases in Combivent<sup>®</sup> and Atrovent<sup>®</sup>, branded products containing the active ingredient ipratropium. Prices for both products increased by 21.9 percent in 2002. Prices for the market share leaders in the class, Singulair<sup>®</sup> and Advair Diskus<sup>®</sup>, rose 5.9 percent and 9.4 percent, respectively.

The class with the highest brand inflation rate was cephalosporins, which are used to treat bacterial infections. The price for the leading brand in the class, Cefzil<sup>®</sup>, grew 13.4 percent in 2002. The price for Ceftin<sup>®</sup>, which went generic in 2002, increased by 7.1 percent.

Inflationary increases for other anti-infective classes, penicillins and macrolides, were much lower than for cephalosporins. The brand market share for penicillins continued to be dominated by Augmentin<sup>®</sup>, the price of one strength of which rose by 4 percent. Some strengths of Augmentin<sup>®</sup> came out in generic form in 2002. Among macrolides, the price of the most frequently dispensed version of Zithromax<sup>®</sup> increased 5 percent, and the price of Biaxin<sup>®</sup> XL, the newest formulation in the Biaxin<sup>®</sup> family, rose by 4.1 percent in 2002.

Estrogens and thyroid products continued to rank in the top 10 in 2002. Estrogens, while remaining in the same rank position as last year, increased 2.8 percentage points more than last year. Increases for the most commonly dispensed strengths of the estrogen market leader, Premarin<sup>®</sup>, ranged from 17.5 percent to 23.9 percent. The price increase for the combination estrogen-progestin product Prempro<sup>®</sup> 0.625-2.5 MG, the second most used product in the class, was 10 percent. Thyroid products experienced the largest decline in the rate of price increase for any of the top 25 therapeutic classes. The 9.2 percent price increase was 10.2 percentage points lower than in 2001. This was primarily due to the relatively small 6.7 percent increase seen for Synthroid<sup>®</sup> 100MCG. Synthroid<sup>®</sup> is the dominant product in the class with over 60 percent of market share. In contrast, the inflation rate for generic thyroid products rose 18.8 percent. This increase was led by the branded generic, Levoxyl<sup>®</sup>, with a 20.1 percent increase. Two other classes of drugs devoted to caring for women's health — contraceptives and miscellaneous endocrines — experienced relatively low inflationary increases of 6.9 percent and 4.7 percent, respectively.

Ophthalmic products ranked sixth in the magnitude of price increases, in large part due to a 10.6 percent rise in prices of brand ophthalmic products. Brand ophthalmics can be grouped into three basic categories: products used to treat glaucoma (eye pressure), products used to treat itchiness associated with allergies and products used to treat infections. Of these categories, products used to treat infections increased in price the most. Ciloxan<sup>®</sup> and Ocuflox<sup>®</sup>, both quinolone antibiotics, increased 18.2 percent and 14.5 percent, respectively. The price of Tobradex<sup>®</sup>, a different type of antibiotic, increased 18.4 percent. By comparison, the price rises were 5.9 percent for Xalatan<sup>®</sup>, the most frequently dispensed glaucoma product, and 9.2 percent for the most frequently dispensed allergy symptom reliever, Patanol<sup>®</sup>.

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Increases in brand prices were also seen among anticonvulsants, with brand inflation rising 9.8 percent. Prices for the most widely dispensed strengths of Neurontin<sup>®</sup>, the brand commanding 26.3 percent of the market share in the class, grew by 10.5 percent in 2002. Topamax<sup>®</sup>, the product with the biggest market share growth in the class at 7 percent, increased in price by 16.3 percent in 2002.

Dermatological brand price increases reached double figures in 2002, increasing by 10.5 percent. Bactroban<sup>®</sup>, the most frequently dispensed brand in the class, increased only 6 percent. However, this modest price rise was offset by increases of 13.1 percent for the acne medication, Differin<sup>®</sup> and 44.2 percent for the topical antiviral, Zovirax<sup>®</sup>.

Gastrointestinal drugs increased in price by 8.7 percent, with brand prices growing 9.6 percent. Of the top four proton pump inhibitors, only the Prilosec<sup>®</sup> price increase, 7.3 percent, was less than 10 percent.

None of the drug classes used to treat cardiac conditions fell into the top 10 highest in terms of inflation. The only outlier was branded diuretics. This was due to the 9.4 percent increase in the price of Demadex<sup>®</sup>, which went generic in 2002. However, due to heavy generic use in this class, the Demadex<sup>®</sup> price increase did not have a significant impact on the class as a whole.

Classes used to treat conditions affecting the central nervous system (CNS) also did not appear in the top 10 highest in terms of inflation. These classes include antidepressants at 7 percent and anti-anxiety agents at 5.6 percent. Of note, however, was the 6.5 percent increase in the cost of generic anti-anxiety agents. This increase was driven by an average increase of almost 250 percent in the product hydroxyzine, an antihistamine used to treat hives, motion sickness and insomnia, as well as anxiety. This extraordinary price hike occurred as several generic manufacturers dropped out of the market, leaving only one producer.

Similarly, no classes with primary indications in pain relief, including anti-rheumatics (NSAIDs) and narcotic analgesics, had unusually high inflation increases. Among NSAID brands, a 19.8 percent increase occurred in the price for the most commonly used strength of Mobic<sup>®</sup>, a relatively new drug on the market. However, because of the modest 3 percent market share held by Mobic<sup>®</sup>, its impact on the overall class inflation rate was minor. Among COX-2s, the most commonly dispensed drugs in the class, competitive pressures kept all products below a 7 percent increase.

Within the narcotic analgesics class, the price for Ultram<sup>®</sup> rose by 24.9 percent, even though Ultram<sup>®</sup> went generic in mid-2002. The price for its sister product, Ultracet<sup>®</sup>, increased by 14.6 percent. In this class, with a generic fill rate approaching 70 percent, generic prices increased on average by only 1.5 percent.

**Drug Mix**

The impact of mix on changes in the cost per prescription was analyzed in terms of therapeutic mix and brand/generic mix. Therapeutic mix is the use of relatively more expensive or less expensive drugs, and drug strengths within and across therapy classes. Brand/generic mix refers to cost changes caused by shifts from brands to their respective generic equivalents both within and across therapy classes.

**Therapeutic Mix**

The 5.3 percent therapeutic mix trend in 2002 was a little higher than the 4.4 percent seen in 2001. As has been the case in past years, significant variability in therapeutic mix existed across therapy classes in 2002. On one extreme, the therapeutic mix trend was negative in nine classes, and on the other it was over 5 percent in four classes.

**Table 5**  
**Price Changes Due to Therapeutic Mix for the Top 25 Therapy Classes 2001-2002**

RANK	THERAPY CLASS	THERAPEUTIC MIX % CHANGE
1.	Asthmatics	12.3%
2.	Anticonvulsants	8.7%
3.	Narcotic Analgesics	7.1%
4.	Anticholinergics	6.1%
5.	Cardiac Products	4.8%
6.	Antihyperlipidemics	4.2%
7.	Antihypertensives	3.4%
8.	Antidepressants	2.6%
9.	Penicillins	2.4%
10.	Beta Blockers	2.2%
11.	Gastrointestinals	1.7%
12.	Calcium Blockers	1.2%
13.	Decongestants	1.0%
14.	Anti-Rheum (NSAIDs)	0.6%
15.	Misc. Endocrine	0.5%
15.	Oral Contraceptives	0.4%
17.	Thyroid	-0.4%
18.	Antiemetic Agents	-0.7%
19.	Diuretics	-0.8%
20.	Macrolides	-0.9%
21.	Cephalosporins	-1.7%
22.	Antihistamines	-2.5%
23.	Dermatologics	-2.5%
24.	Cough/Cold	-2.9%
25.	Estrogens	-4.7%
	Top 25	4.3%
	Other	9.2%

The drug which contributed the most to the 12.3 percent mix increase in antiasthmatics was Advair Diskus<sup>®</sup>, a relatively new combination product containing the active ingredients of two other asthma drugs, Flovent<sup>®</sup> and Serevent<sup>®</sup>. While Advair Diskus<sup>®</sup> was one of the most expensive products in the class at \$124.09 per inhaler, this price was less than the combined price of Flovent<sup>®</sup> and Serevent<sup>®</sup>. Also, the switch to Advair Diskus<sup>®</sup> was the primary reason for the decline in intensity, or prescriptions per person, in this class due to patients requiring only one prescription rather than two. Another contributor to the mix increase in this class, although not to the extent of Advair Diskus<sup>®</sup>, was Singulair<sup>®</sup>. Like Advair Diskus<sup>®</sup>, Singulair<sup>®</sup> is indicated for the prevention of asthma attacks, not for acute therapy. In addition, Singulair<sup>®</sup>, which received an indication for allergic rhinitis in 2003, likely was used more frequently for such off-label conditions in 2002.

The second highest ranked class in terms of therapeutic mix was anticonvulsants, which saw an 8.7 percent increase in 2002. While no one product increased market share to the extent seen within the antiasthmatic class, all six of the anticonvulsant drugs that had average costs of more than \$100 per prescription in 2002, gained market share. These drugs are characterized by their use in treating a broad range of conditions other than seizures. The most frequently prescribed anticonvulsant, Neurontin<sup>®</sup>, often used to treat pain, saw its market share rise 0.9 percent. Topamax<sup>®</sup>, used to prevent migraines, gained 2.4 market share points. At \$162.22 per prescription, the cost for Topamax<sup>®</sup> was almost twice the therapy class average price of \$82.73.

Narcotic analgesics were the third highest class in terms of mix trend at 7.1 percent. This high mix trend was due primarily to Duragesic<sup>®</sup>, which rose in market share by only 0.2 percent but which carries a price that is over seven times the class average. Also contributing to the mix increase was a 0.9 percent increase in the market share of tramadol products, which include Ultram<sup>®</sup>, tramadol-generic and Ultracet<sup>®</sup>.

The fast class with mix trend greater than 5 percent was antidiabetics. Market share increases were seen among the most expensive oral products and the most expensive insulin products. Among oral antidiabetics, Actos<sup>®</sup> and Avandia<sup>®</sup> increased market share by 1.3 percent and 0.2 percent, respectively. The average per prescription cost for Actos<sup>®</sup> was 2.3 times the average cost in the class, while the cost of Avandia<sup>®</sup> was 1.9 times greater than the class average. Among insulins, Humalog<sup>®</sup> and Novolog<sup>®</sup> continued to take market share from Humulin<sup>®</sup> and Novolin<sup>®</sup>. These newer products cost about twice as much as their predecessors but deliver insulin much faster, thereby simplifying many of the timing issues associated with injecting insulin at meal times.

Classes with the greatest negative mix trend were ones in which the previous market leader fell out of favor due to negative publicity or loss of marketing support. In the case of estrogens, which experienced a 4.7 percent drop in mix trend, adverse publicity about the side effects of combination estrogen/progestin products contributed to market share declines of 3.7 percent and 0.2 percent for Prempro<sup>®</sup> and Premphase<sup>®</sup>, respectively. Likewise, in the dermatological class, concerns about the safety of Accutane<sup>®</sup> (and all isotretinoin products) precipitated a 0.5 percent drop in isotretinoin market share. This relatively small decrease was magnified by the cost of Accutane<sup>®</sup>, which at \$414.14 per prescription was 8.4 times the class average.



Antihistamines and cough/cold products had similar mix trend decreases in 2002 due to precipitous declines in the Claritin® franchise. In both classes, Claritin® products were the most frequently dispensed as well as the most expensive products in their respective classes in 2001. In 2002, however, Claritin® dropped 8.4 points largely to the new drug Clarinex®, made by the same manufacturer. As a byproduct, market shares for the remaining non- and low-sedating common drug products Allegra® and Zyrtec® rose by 5.5 percent and 1.9 percent, respectively. In the cough/cold class, Claritin-D® 24 Hour and Claritin-D® 12 Hour dropped a combined 4 percent. Since no follow-on product was produced by the manufacturer of Claritin-D®, this lost market share was captured by Allegra-D® and Zyrtec-D®.

#### Brand/Generic Mix

The overall brand/generic mix was -2.3 percent, as 22 of the top 25 therapy classes experienced a decline in brand/generic mix trend. In general, the financial impact of a new generic on annual drug trend depends on the price of the brand relative to the generic equivalent, the speed of converting the predecessor brand to its generic equivalent (generic conversion rate), the date the generic was introduced and the original market share of the brand. The remainder of this section outlines the effect that the introductions of significant new generics have had in reducing prescription drug costs.

Table 6  
Brand/Generic Mix for the Top 25 Therapy Classes 2001-2002

RANK	THERAPY CLASS	% CHANGE
1.	Antiemetic Agents	-3.1%
2.	Antidiabetics	-7.6%
3.	Penicillins	-5.0%
4.	Narcotic Analgesics	-5.6%
5.	Oral Contraceptives	-5.5%
6.	Antidepressants	-5.1%
7.	Cephalosporins	-5.0%
8.	Antihypertensives	-4.6%
9.	Diuretics	-2.8%
10.	Anti-Rheum (NSAIDs)	-2.0%
11.	Calcium Blockers	-2.0%
12.	Cough/Cold	-1.7%
13.	Dermatologicals	-1.5%
14.	Gastrointestinals	-1.2%
15.	Thyroid	-1.1%
16.	Ophthalmic Products	-1.0%
17.	Anticoagulants	-0.8%
18.	Antihyperlipidemics	-0.6%
19.	Anticholinergics	-0.5%
20.	Antihistamines	-0.2%
21.	Estrogens	-0.2%
22.	Decongestants	-0.1%
23.	Macrolides	0.1%
24.	Misc. Endocrine	0.1%
25.	Beta Blockers	0.0%
	Top 25	-2.5%
	Other	-1.3%

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Appendix B	Appendix A	Actions	Specialty Injectables	Cost Forecast	TRENDS IN EXPENDITURES	Introduction	Preface	Table of Contents
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The highest brand/generic mix was in the antianxiety class, -9.1 percent. The key factor that made antianxiety agents the leader in brand/generic mix was the substantial price difference between BuSpar® and its generic, buspirone. The 18.5 percent AWP difference between the brand and the generic was much higher than the 10 percent typically seen for new generics.

The substantial -7.6 brand/generic mix in the antidiabetic class was driven largely by the conversion of Glucophage® to metformin. About 90 percent of Glucophage® prescriptions were converted to metformin within 6 months of the generic's entry into the market in late January 2002.

The brand/generic mix of -6 percent for penicillins was due to the introduction of generics for some strengths of Augmentin®. Generics for Augmentin® did not achieve maximum impact in 2002, largely because the introduction came on the heels of an unexpected loss of a patent infringement lawsuit by the brand manufacturer. This decision resulted in supply shortages in the first few months of generic availability and, consequently, a slower generic uptake.

The introduction of tramadol, the generic for Ultram®, led to the -5.6 percent brand/generic mix in the narcotic analgesic class. Tramadol was produced by multiple manufacturers shortly after generic launch, and a 90 percent generic conversion was achieved within 5 months. The factors keeping the brand/generic mix for narcotic analgesics from being even higher were the relative low (6.9 percent in 2001) market share for Ultram® and a mid-year launch for tramadol.

The -5.5 percent brand/generic mix for oral contraceptives was achieved despite a slow uptake for generic Loestrin Fe®. Slower uptake is typically seen for contraceptives because of the wide range of products in the class and the branding of the generic (Microgestin® FE), which blurs the differentiation between the brand and generic versions.

The brand/generic mix for antidepressants was -5.1 percent. This significant brand/generic mix was largely driven by the use of fluoxetine, the generic for Prozac®.

The impact of the generic for Ceftin®, at -5 percent, was enough to capture seventh place for cephalosporins in the brand/generic mix ranking. However, two factors kept this impact from being greater. First, only Ceftin® tablets and capsules went generic in 2002 accounting for an overall slower generic uptake than if all Ceftin® dosage forms had gone generic at the same time. Second, the overall market share of generic and brand Ceftin® decreased from 13.3 percent in 2001 to 11.4 percent in 2002.

The launch of lisinopril, the generic for the co-branded products Zestril® and Prinivil®, resulted in one of the fastest conversions ever seen for a new generic. A 90 percent conversion was achieved in 4 months. Only the mid-year launch of the generic prevented the antihypertensive class from a higher ranking among the top eight classes. Yet the -4.6 percent brand/generic mix was still considerable.

As the impact of new generics on trend is analyzed for other classes, market share dynamics and release dates must be considered. For example, diuretics were already more than 80 percent generic, so the introduction of a generic for Demadex® did not have a major effect on the class, which had a -2.8 percent brand/generic mix. Among anti-rheumatics, COX-2s have largely supplanted traditional NSAIDs as the drugs of choice, thereby dampening the impact of generic Relafen® (-2 percent brand/generic mix). In the antihyperlipidemic class, Mevacor® lost market share as its manufacturer shifted marketing efforts to Zocor®. So again, the result of a new generic was not as significant, leading to only a -0.6 percent brand/generic mix.

The launch of the branded generic for Accutane®, Amnesteem®, was hampered by strict labeling requirements warning of potential safety issues with all oral isotretinoin products — both brand and generic. This disadvantage, coupled with a late 2002 release date, reduced the impact of the generic to a -1.6 percent brand/generic mix in the dermatological class.

Within the gastrointestinal class, the mid-December release date of the generic for Prilosec® lessened the effect of this release on the brand/generic mix to only -1.2 percent. The generic for Acid®, a member of the H2 category of drugs that had significant decreases in utilization in favor of PPIs, contributed to most of the trend impact because it was released in mid-2002.

At the other end of the brand/generic mix spectrum was the beta blocker class. In this class the brand/generic mix was positive, at 0.5 percent. This is indicative of market share moving back to a brand version of a drug when an established generic is already on the market. This unexpected event actually occurred due to a supply shortage in 2002 of long-acting propranolol capsules. In this case, the brand, Inderal LA®, became more readily available, so it was dispensed in a greater proportion than the generic.

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**Units Per Prescription**

The -0.1 percent difference in the cost per prescription due to changes in the number of units per prescription was the first time that this factor was negative since the inception of the *Drug Trend Report* in 1997.

Table 7  
Changes in Units Per Prescription for the Top 25 Therapy Classes 2001-2002

Ranked by Percent Change

RANK	THERAPY CLASS	% PRESCRIPTIONS	% CHANGE
1.	Narcotic Analgesics	4.1%	4.7%
2.	Cough/Cold	2.8%	3.7%
3.	Dermatologicals	2.7%	2.1%
4.	Macrolides	1.6%	1.7%
5.	Anti-Rheum (NSAIDs)	3.4%	1.1%
6.	Decongestants	1.4%	1.0%
7.	Acid/Alkalies	3.9%	0.7%
8.	Beta Blockers	3.8%	0.6%
9.	Antihistamines	3.0%	0.5%
10.	Estrogens	3.9%	0.5%
11.	Anxiolytic Agents	1.9%	0.5%
12.	Penicillins	2.6%	0.2%
13.	Oral Contraceptives	3.5%	0.0%
14.	Calcium Blockers	2.8%	-0.1%
15.	Antihypertensives	7.6%	-0.2%
16.	Gastrointestinals	4.5%	-0.4%
17.	Anticancer drugs	3.3%	-0.4%
18.	Thyroid	3.1%	-0.4%
19.	Antihyperlipidemics	5.8%	-0.7%
20.	Anticonvulsants	1.5%	-0.8%
21.	Diuretics	3.3%	-1.1%
22.	Misc. Endocrine	1.4%	-1.5%
23.	Ophthalmic Products	1.4%	-2.0%
24.	Antidepressants	6.4%	-2.0%
25.	Cephalosporins	1.1%	-3.5%
	Top 25	81.5%	0.0%
	Other	18.6%	-0.5%

Leading the negative trend in units per prescription were some classes of antibiotics. This trend may be a result of changes in dosing recommendations — particularly for drugs in the cephalosporin and macrolide classes. Several of these drugs are just as effective when used for shorter periods, but compliance is improved and the risk of resistance is reduced. For example, the macrolide Zithromax® is used for only 5 days for many infections. Some spillover into other classes of antibiotics may be occurring.

The negative trend in units per prescription for antidepressants may be explained by the recent availability of products such as Prozac® Weekly™ and Paxil CR™. These long-acting products are taken by patients who previously would have required prescriptions with a greater unit count. Patients who take shorter-acting antidepressants still require prescriptions for one or more units per day.

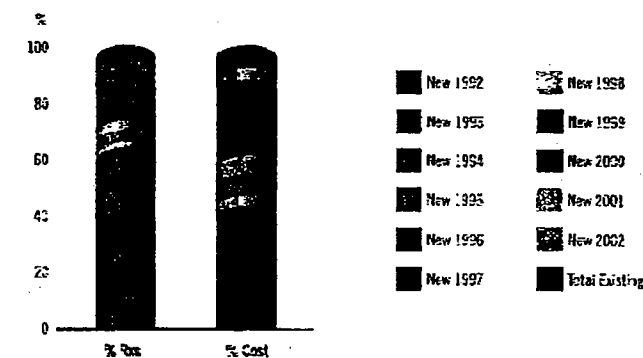
Classes with the greatest increase in units trend are narcotic analgesics, cough/cold products and dermatologicals. All three classes consist of products generally taken on an "as needed" basis, rather than for a specified period of time. These three classes consistently rank among the top five classes in units trend.

### New Drugs

Drugs introduced in 1992 and thereafter accounted for 57.7 percent of 2002 PMPY costs and 36.2 percent of total 2002 PMPY utilization (see Figure 7). In contrast to the robust cumulative impact that new drugs introduced between 1992 and 2001 had on 2002 costs and utilization, the annual impact of drugs introduced in 2002 was marginal. Drugs introduced in 2002 accounted for only one percent of the overall 18.5 percent 2002 trend. Ninety percent of this contribution was due to the utilization of these new drugs, with the remaining 10 percent attributable to added costs per prescription (see Table 8). This relatively small percentage continued a downward trend that began in 1997. Following the FDA's approval of 24 new drugs<sup>26</sup> and eight new biologics<sup>27</sup> in 2001, only 17 new drugs<sup>28</sup> and nine new biologics<sup>29</sup> were approved in 2002 — the lowest number of new drug approvals since 1983.

Figure 7

Impact of New Drugs Introduced Since 1992 on 2002 Utilization and Ingredient Cost



26 Center for Drug Evaluation and Research, U.S. Food and Drug Administration, NMEs approved in calendar year 2001. Published January 2002. Available at: [www.fda.gov/cder/drug/ndm/2001/2001.htm](http://www.fda.gov/cder/drug/ndm/2001/2001.htm). Accessed February 27, 2002.

27 Center for Biologicals Evaluation and Research, U.S. Food and Drug Administration, 2001 Biological License Application Approvals. Last Updated January 31, 2003. Available at: <http://www.fda.gov/cber/app/2001/2001.htm>. Accessed March 25, 2003.

28 Center for Drug Evaluation and Research, U.S. Food and Drug Administration, NMEs approved in calendar year 2002. Available at: [www.fda.gov/cder/drug/ndm/2002/2002.htm](http://www.fda.gov/cder/drug/ndm/2002/2002.htm). Accessed February 21, 2003.

29 Center for Biologicals Evaluation and Research, U.S. Food and Drug Administration, 2002 Biological License Application Approvals. Last Updated January 31, 2003. Available at: <http://www.fda.gov/cber/app/2002/2002.htm>. Accessed March 25, 2003.

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Table 6  
Top New Drugs in 2002

RANK	DRUG NAME	ROUTE	FDA APPROVAL DATE	PRIMARY INDICATION	% INGREDIENT	
					COST	PMPY COST
1.	CLARINEX*	PO	9-Feb-02	Allergic Rhinitis	0.33%	\$1.93
2.	BEXTRA*	PO	16-Nov-01	Arthritis	0.26%	\$1.54
3.	LEXAPRO*	PO	14-Aug-02	Depression	0.05%	\$8.26
4.	ELIQUIS*	TP	13-Dec-01	Atopic Dermatitis	3.04%	\$0.26
5.	NEULASTA*	SC	31-Jan-02	Leukopenia	0.03%	\$9.19
6.	ORTHO EVRA*	TD	20-Nov-01	Contraception	0.02%	\$0.12
7.	ADVICOR*	PO	17-Dec-01	Elevated Cholesterol	0.01%	\$0.09
8.	BERNEM*	PO	25-Apr-02	Hypertension	0.01%	\$0.05
9.	ZELNORM*	PO	23-Jul-02	Irritable Bowel Syndrome	0.01%	\$0.05
10.	FRONIA*	PO	8-Nov-01	Migraine Headache	0.01%	\$0.04
11.	TRI-LUMA*	TP	18-Jan-02	Skin Discoloration	0.01%	\$0.03
12.	ZETA*	PO	25-Oct-02	Elevated Cholesterol	0.01%	\$0.03
13.	SUBUTEX*	SL	8-Oct-02	Opioid Dependence	0.00%	\$0.02
14.	VIFEND*	PO	24-May-02	Fungal Infection	0.00%	\$0.02
15.	FOCALIN*	PO	13-Nov-01	Attention-Deficit Hyperactivity Disorder	0.00%	\$0.01
16.	AVANDAMET*	PO	10-Oct-02	Diabetes	0.00%	\$0.01
17.	NULVING*	VG	3-Oct-01	Contraception	0.00%	\$0.01
18.	ABILIFY*	PO	15-Nov-02	Psychosis	0.00%	\$0.01
19.	NOVOLOG MIX 70/30*	SC	1-Nov-01	Diabetes	0.00%	\$3.01
20.	FASLODEX*	IV	25-Apr-02	Breast Cancer	0.00%	\$0.20
Top 20 New Drugs					0.31%	\$4.72
All New Drugs					0.07%	\$5.07
All Other Drugs					99.62%	\$596.92

PO - Oral; TP - Topical; SC - Injected under the skin; TD - Transdermal; SL - Sublingual; VG - Vaginal; IV - Intravenous

Only a couple of the products introduced in 2002 had a significant impact on total 2002 PMPY costs. Clarinex<sup>®</sup>, an active metabolite of Claritin<sup>®</sup> that is indicated for the treatment of allergies, was brought to market in early 2002. The patent for Claritin<sup>®</sup> expired in December 2002 and Claritin<sup>®</sup> is now available only in the OTC setting. In the period between the market entry of Clarinex<sup>®</sup> and the patent expiration date of Claritin<sup>®</sup>, the manufacturer attempted to convert Claritin<sup>®</sup> users to Clarinex<sup>®</sup>. These efforts resulted in a Clarinex<sup>®</sup> market share of 9.3 percent, despite its being on the market for only about three-quarters of the year; in contrast, Claritin<sup>®</sup> lost 11.2 percentage points in market share between 2001 and 2002. Because of the late date in the plan year that OTC Claritin<sup>®</sup> and other OTC loratadine products came to market, few plan sponsors changed their coverage rules for the antihistamine class. For the 2004 plan year, individual plan sponsors may choose to stop coverage of prescription antihistamine products, charge a higher copayment for those prescription products, cover the OTC products or adopt some combination of these options.

Bextra<sup>®</sup> (valdecoxib) is a COX-2 inhibitor used for the treatment of pain and inflammation. Although it does not appear to have a clear clinical advantage compared to the other COX-2 inhibitors (Vioxx<sup>®</sup> and Celebrex<sup>®</sup>), Bextra<sup>®</sup> may offer an additional therapeutic alternative when a COX-2 inhibitor is

appropriate as well as for those who cannot tolerate or do not receive an adequate response from the other COX-2 inhibitors. Despite being introduced several months into the year, Bextra<sup>®</sup> still managed to capture a 4.5 percent market share in the anti-rheumatics (NSAID) class.

Lexapro<sup>®</sup> (escitalopram) is a refined version of Celexa<sup>®</sup> (citalopram), used for the treatment of depression. The product was brought to market as Celexa<sup>®</sup> nears patent expiration in January 2004.

Zetia<sup>®</sup> (ezetimibe) is the first in a new class of cholesterol-lowering medications that blocks the absorption of cholesterol from the gastrointestinal tract. It may be used alone or in combination with a statin to help attain target cholesterol levels. Zetia<sup>®</sup> provides another treatment option for individuals who cannot tolerate or achieve cholesterol goals with other therapies. This drug is also being studied as a combination product with a statin as a single, once-daily dosage form for the treatment of high cholesterol. Additional cholesterol reducing products introduced in 2002 include Advicor<sup>®</sup> and Altacor<sup>®</sup>. Both of these products contain the statin drug lovastatin, and they were marketed after a key patent for Mevacor<sup>®</sup> (lovastatin) expired in December 2001. Advicor<sup>®</sup> combines long-acting niacin with lovastatin, while Altacor<sup>®</sup> is an extended-release lovastatin formulation to allow for once-daily dosing at all approved strengths.

Abilify<sup>®</sup> (aripiprazole) represents another option for the treatment of schizophrenia, especially for those who are resistant to or cannot tolerate current therapies. Because it was approved in November 2002, its impact on the 2002 drug trend is minimal.

Humira<sup>®</sup> (adalimumab) is another biologic TNF-alpha blocker used to treat rheumatoid arthritis. This product requires a self-administered subcutaneous injection once every other week. It will compete with current biologic agents, Enbrel<sup>®</sup> and Kineret<sup>®</sup>. The future growth of this class will be due to expanded indications for TNF-alpha blockers for the treatment of other diseases (e.g., psoriasis and ankylosing spondylitis, which is rheumatoid arthritis of the spine). Because Humira<sup>®</sup> was approved on the last day of 2002, it did not impact the 2002 drug trend.

Despite the low number of new drug approvals over the last several years, the impact of drugs brought to market during the past 11 years contributed significantly to 2002 PMPY costs. As shown in Figure 8 and Table 9, new drugs generally peak in cost impact 5 or 6 years after reaching the market — provided that they have patent life remaining. Moreover, the cumulative magnitude of the cost impact from new products depends on whether or not they grow into blockbusters. Thus, the effect of blockbuster drugs introduced in 1992, 1995 and 1997 in particular accounted for a significant portion of 2002 PMPY costs. After reaching maximum cost impact in 1997, drugs brought to market in 1992 still accounted for 8 percent of 2002 costs, primarily driven by the contributions of Zolof<sup>®</sup>, Zocor<sup>®</sup>, Norvasc<sup>®</sup> and Zithromax<sup>®</sup>. Drugs introduced in 1995 contributed 9.1 percent to 2002 PMPY ingredient costs, the most of any year of introduction and at a level that has remained constant since 2000. Key products introduced in that year include Prevacid<sup>®</sup>, Glucophage<sup>®</sup>, Prempro<sup>®</sup> and Ultram<sup>®</sup>. The contribution made to 2002 costs remained substantial despite the lower cost associated with the generic versions of Glucophage<sup>®</sup> and Ultram<sup>®</sup> that went generic in 2002. Drugs introduced in 1997 contributed 9 percent to overall 2002 PMPY ingredient costs — including 4.7 percent contributed by Lipitor<sup>®</sup>, the key product introduced in 1997. Other key drugs introduced in that year were Levaquin<sup>®</sup>, Diovan<sup>®</sup> and Topamax<sup>®</sup>.

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Appendix B	Actions	Specialty Injectables	Cost Forecast	Introductions	Prescriptions	Table of Contents
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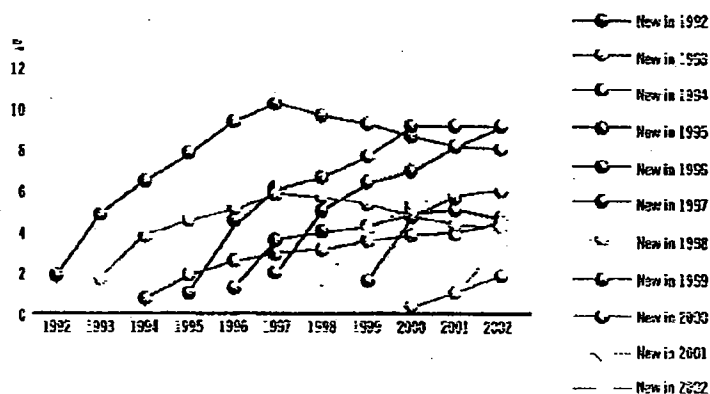
Table 9

Percent of 2002 Ingredient Cost and Cost Per Prescription for the Top 50 New Drugs Introduced Since 1992

RANK	BRAND NAME	YEAR OF INTRODUCTION	% 2002 COST	2002 COST/Rx
1.	LIPITOR <sup>®</sup>	1997	4.55%	\$75.49
2.	PREVACID <sup>®</sup>	1995	2.85%	\$128.69
3.	ZOCOR <sup>®</sup>	1992	1.84%	\$106.04
4.	CELEBREX <sup>®</sup>	1999	1.59%	\$96.77
5.	NEULAM <sup>®</sup>	2001	1.58%	\$120.59
6.	ZOLOFT <sup>®</sup>	1992	1.55%	\$75.40
7.	PAXIL <sup>®</sup>	1993	1.51%	\$79.86
8.	CLARITIN <sup>®</sup>	1993	1.37%	\$78.77
9.	VIOXX <sup>®</sup>	1999	1.26%	\$79.76
10.	ALLEGRA <sup>®</sup>	1996	1.15%	\$60.61
11.	EFFEXOR <sup>®</sup>	1994	1.09%	\$98.51
12.	NORVASC <sup>®</sup>	1992	1.07%	\$47.71
13.	CELEXA <sup>®</sup>	1998	1.05%	\$67.22
14.	GLUCOPHAGE <sup>®</sup>	1995	0.98%	\$46.61
15.	NEURONTIN <sup>®</sup>	1994	0.93%	\$15.24
16.	FOSAMAX <sup>®</sup>	1995	0.89%	\$60.30
17.	ACTOS <sup>®</sup>	1999	0.85%	\$132.43
18.	ZITHROMAX <sup>®</sup>	1992	0.84%	\$37.63
19.	SINGULAIR <sup>®</sup>	1999	0.82%	\$76.72
20.	ZYRTEC <sup>®</sup>	1996	0.79%	\$50.40
21.	ROMUCODONE <sup>®</sup>	1992	0.71%	\$128.10
22.	AVANDIA <sup>®</sup>	1999	0.69%	\$110.23
23.	AMBIEN <sup>®</sup>	1993	0.67%	\$60.39
24.	HYZARE <sup>®</sup>	1995	0.65%	\$48.59
25.	P.A.M.X <sup>®</sup>	1996	0.63%	\$108.94
26.	PHIREX <sup>®</sup>	1995	0.63%	\$178.57
27.	PREMPRO <sup>®</sup>	1995	0.59%	\$28.96
28.	AVONEX <sup>®</sup> ADMINISTRATION PACK	1996	0.59%	\$906.28
29.	PROTONIX <sup>®</sup>	2000	0.57%	\$94.92
30.	FLONASE <sup>®</sup>	1999	0.56%	\$56.45
31.	ACIPHEX <sup>®</sup>	1999	0.55%	\$119.99
32.	REBETOL <sup>®</sup>	2001	0.54%	\$1,347.76
33.	EMBREL <sup>®</sup>	1998	0.53%	\$1,105.15
34.	LEVAQUIN <sup>®</sup>	1997	0.53%	\$79.59
35.	LOTREL <sup>®</sup>	1995	0.45%	\$61.55
36.	PEG-INTRON <sup>®</sup>	2001	0.45%	\$1,086.35
37.	EVISTA <sup>®</sup>	1998	0.39%	\$63.76
38.	ACCUTANE <sup>®</sup>	1992	0.38%	\$413.18
39.	DIOVAN <sup>®</sup>	1997	0.37%	\$43.30
40.	VIAGRA <sup>®</sup>	1998	0.36%	\$54.42
41.	ASACOL <sup>®</sup>	1992	0.35%	\$166.87
42.	FLOVENT <sup>®</sup>	1996	0.35%	\$71.73
43.	BIPHENHYDRA <sup>®</sup>	1992	0.35%	\$71.22
44.	VALTREX <sup>®</sup>	1995	0.34%	\$190.95
45.	NASCNEX <sup>®</sup>	1997	0.34%	\$57.45
46.	LAMISIL <sup>®</sup>	1996	0.34%	\$221.65
47.	TOPAMAX <sup>®</sup>	1997	0.34%	\$162.22
48.	RISPERDAL <sup>®</sup>	1994	0.33%	\$145.97
49.	CLARINEX <sup>®</sup>	2002	0.32%	\$56.72
50.	TRICOR <sup>®</sup>	1996	0.32%	\$64.26
	OTHER		57.27%	\$40.72



Figure 8  
Percent of Ingredient Cost Accounted for by New Drugs Introduced Since 1992



Drugs introduced in 1998 and 1999 contributed about 6 percent to 2002 costs, and their respective contributions continue to grow. Key products introduced in 1998 include Celebra<sup>®</sup>, Singulair<sup>®</sup>, Enbrel<sup>®</sup>, Plavix<sup>®</sup>, Evista<sup>®</sup> and Viagra<sup>®</sup>. The dollar impact of drugs introduced in 1999 on 2002 costs is concentrated in a few products. Celebrex<sup>®</sup> and Vioxx<sup>®</sup> accounted for 2.8 percent of 2002 costs, with Actos<sup>®</sup> and Avandia<sup>®</sup> contributing 1.5 percent to these costs. In contrast, drugs brought to market in 2000 contributed a minimal 1.8 percent to 2002 costs, with the only significant drug introduced in that year being Protonix<sup>®</sup>. A few new products introduced in 2001 accounted for a significant percentage of 2002 costs. These products, Nexium<sup>®</sup>, PEG-Intron<sup>®</sup> and Rebetal<sup>®</sup>, together contributed 2.9 percent to 2002 costs, and they are expected to have a greater impact in 2003.

Over the next several years, the number of new drugs potentially entering the marketplace is similar to levels seen in the recent past. According to SG Cowen<sup>30</sup>, 1,084 products are in the development pipeline, compared with 1,050 and 1,010 for the previous two years, respectively. Of these products, 212 are in preclinical study, 743 are in phase I, II or III clinical trials, and the applications for another 129 have been filed with the FDA. These numbers were 191, 707 and 152, respectively, for the previous year. However, few blockbusters are expected to result from this pipeline in the near future.

30 SG Cowen Securities, *Pipeline Puts*, October 2002.

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### Summary

PMPY ingredient costs increased by 18.5 percent to \$585.60 in 2002. It should again be noted that this year's Report expresses PMPY ingredient costs as AWP less 12 percent for brands and AWP less 36 percent for generics. In contrast, previous editions of the Report considered ingredient costs as full AWP costs. More than 60 percent of this rise was due to higher per prescription costs, 34.2 percent was attributable to increased utilization and 5.3 percent to medicines brought to market in 2002. The inflation rate grew by 7.5 percent, accounting for 43.4 percent of the overall 2001-2002 PMPY expenditure increase. A little more than one-half of the utilization increase is due to more prescriptions per utilizer and the remainder to more members using prescription drugs.

The magnitude of the 2002 PMPY ingredient cost for a given class generally translates into the proportion of total PMPY costs attributable to that class. The top five therapy classes in terms of costs (gastrointestinals, antihyperlipidemics, antidepressants, antihypertensives and NSAIDs) accounted for 36.8 percent of total 2002 PMPY costs and 39.6 percent of the 2001-2002 cost increase. PMPY costs for the next five classes (antidiabetics, antiasthmatics, antihistamines, antivirals and dermatologicals) represented another 17.1 percent of the overall 2002 PMPY costs and 18.3 percent of the 2001-2002 growth (see Table 10). The overlap between the top 14 classes in terms of 2002 PMPY costs and 2001-2002 cost change is also quite substantial. With only one exception — dermatologicals, which ranked 10th in 2002 costs and 27th in contributing to 2001-2002 cost increases — the top 14 ranked classes on one measure were in the top 14 on the other scale.

Table 10

#### Top 14 Therapy Classes Contributing to 2002 Trend

Ranked by Percent of 2002 Trend Increase

THERAPY CLASS	2002 \$ PMPY	2002 % TREND INCREASE
Gastrointestinals	\$53.60	11.9%
Antihyperlipidemics	\$51.77	10.9%
Antidepressants	\$50.46	8.7%
Antihypertensives	\$30.97	5.0%
Anti-Rheumatic (NSAIDs)	\$28.66	3.2%
Antidiabetics	\$25.66	3.6%
Antiasthmatics	\$22.27	4.5%
Antihistamines	\$21.69	4.2%
Antivirals	\$15.59	5.2%
Dermatologicals	\$14.05	0.7%
Other	\$259.86	42.1%

Just as drug costs are concentrated in relatively few therapy classes, so too are they concentrated among a relatively small number of members. About 58.7 percent of eligible members used the pharmacy benefit in 2002, up from 57.4 percent in 2001. One-third of members used more than one prescription per month, and 11 percent used more than three prescriptions per month. When only the 58.7 percent of members who utilize the pharmacy benefit are considered, fully one-third spend less than \$100 per year, whereas 14 percent spend more than \$1,500 per year. Moreover, 5 percent of members accounted for 50.7 percent of total ingredient costs, and 10 percent of members accounted for 69.7 percent of ingredient costs.

*Cost Forecast*

DRUG TREND

2002 *Report*

## 2003-2007 Drug Cost Trend Forecast

The 18.5 percent increase in PMPY ingredient costs between 2001 and 2002 is the largest annual increase since Express Scripts began monitoring drug trends. It is also higher than the 15.9 percent trend that was predicted in last year's Report. One reason for this discrepancy is the actual 7.5 percent inflation rate versus the 6 percent that was expected. The higher-than-expected inflation rate was particularly evident in the antihistamine, cough/cold and decongestant classes. Last year's projections also underestimated utilization in a couple of key therapeutic classes. For example, PMPY use of proton pump inhibitors was anticipated to grow by 15 percent, but use actually rose by over 24 percent. Similarly, antidepressant and hypnotic utilization grew 16.4 percent and 12.4 percent, respectively, in contrast to their expected 12 percent and 7 percent growth rates. Driven primarily by changes in plan sponsor coverage rules, the use of oral contraceptives also grew faster than expected. One class that grew much faster than projected was antivirals. PMPY cost increases in this class accounted for more than 5 percent of the total PMPY growth in 2002. PMPY cost growth for drugs used to treat hepatitis rose by a substantial 168 percent, driven primarily by the increased use of expensive products like PEG-Intron<sup>®</sup> and Rebetol<sup>®</sup>.

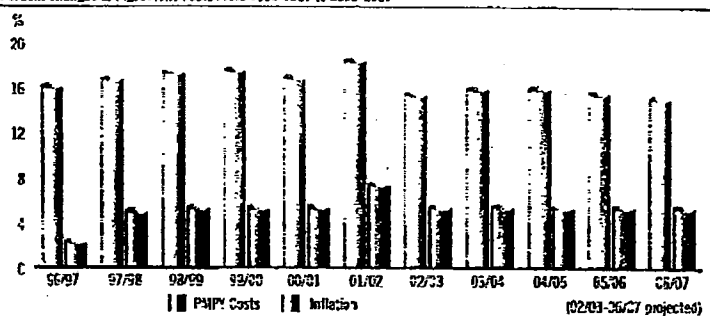
In the remainder of this section, Express Scripts' annual projections for the next 5 years are presented both in the aggregate and for major therapy class groupings. In terms of the former, Express Scripts projects that PMPY ingredient costs will continue to rise but at a reduced and relatively stable rate through 2007. More specifically, Express Scripts projects that drug costs will grow by:

- 15.5 percent in 2003
- 16.0 percent in 2005
- 15.2 percent in 2007
- 15.0 percent in 2004
- 15.6 percent in 2006

These annual projected growth rates translate into PMPY ingredient costs growing by 107 percent over the next 5 years from \$585.50 in 2002 to \$1,212.45 in 2007. Inflation, a key component of overall trend, is projected to grow at 5.5 percent annually through 2007. The relationship between our overall PMPY cost projections and our inflation assumptions is depicted graphically in Figure 9.

Figure 9

Percent Changes in Ingredient Costs From 1996-1997 to 2006-2007



In addition to inflation, other factors in the therapy class specific projections are the aging of the population, anticipated utilization and product mix, introduction of new products and products losing patent status. Express Scripts' annual PMPY cost estimates from 2003 through 2007 are presented in the aggregate and for major therapeutic classes, along with a brief rationale for these projections in Table 11. The remainder of this section presents the major new products anticipated to be marketed and the branded products scheduled to lose patent protection between 2003 and 2007.

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Table 11  
2001-2002 Summary and 2003-2007 Forecast for Major Therapy Classes

THERAPY CLASS	2001 \$PMFY	% CHANGE	2002 \$PMFY	% EST. CHANGE	2003 EST. \$PMFY
<b>Gastrointestinal</b>	\$42.75	25.4%	\$53.89	16.2%	\$41.72
PPis	\$35.41	31.98%	\$46.73	28.5%	\$36.31
<i>Utilization expected to increase at somewhat lower rates. Competition among generic omeprazole manufacturers hard to predict.</i>					
H2s	\$6.18	-9.70%	\$5.58	-3.0%	\$5.42
<i>Utilization will continue to shift to PPIs and OTC products.</i>					
<b>Central Nervous System (CNS)</b>	\$68.81	28.5%	\$82.85	19.3%	\$98.58
Antidepressants	\$42.51	18.7%	\$50.45	18.5%	\$59.80
<i>New indications for existing products will drive up utilization; new brand products will partially offset cost impact of generic Prozac®, Celexa® and Wellbutrin SR®.</i>					
Anticonvulsants	\$10.68	33.5%	\$14.26	25.5%	\$17.99
<i>Use of newer products for epilepsy and use of Neurontin® and its successor pregabalin for pain relief will drive up costs.</i>					
Anxiolytic Agents	\$6.34	1.6%	\$6.44	8.5%	\$6.98
<i>This mostly generic class will experience moderate growth.</i>					
Antipsychotics	\$5.47	26.3%	\$6.94	22.5%	\$8.59
<i>Introduction of Abilify® and expanded uses for existing products will drive up costs.</i>					
Hypnotics	\$3.51	26.3%	\$4.56	18.5%	\$5.40
<i>Not generation of hypnotics expected to come to market and will drive use of this class.</i>					
<b>Cardiovascular</b>	\$51.57	12.1%	\$58.10	10.8%	\$64.42
Antihyperlipidemics	\$41.83	23.8%	\$51.77	20.5%	\$62.39
<i>Utilization expected to continue high growth rates; cost effect of upcoming generics will be somewhat mitigated by new brand products in 2005-2007.</i>					
Antihypertensives	\$26.41	17.3%	\$30.97	13.0%	\$35.80
<i>New ACE inhibitors going generic but utilization will continue at high levels.</i>					
Calcium Blockers	\$13.57	1.2%	\$13.73	3.5%	\$14.21
<i>Declining use of class expected.</i>					
Beta Blockers	\$8.80	19.6%	\$10.53	15.0%	\$12.10
<i>Continued important role of generic-dominated class in treatment of hypertension and heart failure.</i>					
Diuretics	\$2.79	3.3%	\$2.88	8.0%	\$3.11
<i>Recent ALLHAT findings support first-line use for hypertension.</i>					
<b>Pain/Inflammation</b>	\$45.04	15.2%	\$51.80	14.8%	\$59.48
Anti-Rheum (NSAIDs)	\$20.81	0.19%	\$10.83	4.5%	\$11.32
<i>Expect stable use of generic NSAIDs, but more use of NSAIDs (Entra®, Harnia® and Remicade®) will drive up cost per prescription.</i>					
COX-2s	\$14.91	19.57%	\$17.82	15.5%	\$20.59
<i>Use of this class will be pretty stable over the period.</i>					
Narcotic Analgesics	\$12.30	21.9%	\$14.59	19.5%	\$17.32
<i>Utilization growth will moderate, but somewhat greater use of expensive products will drive costs up.</i>					
Migraine Products	\$7.03	17.4%	\$8.25	17.0%	\$9.65
<i>Increased use of prophylactic agents will cause significant class growth.</i>					
<b>Diabetes</b>	\$22.39	14.6%	\$25.86	18.7%	\$30.46
Oral	\$19.24	10.22%	\$20.11	17.5%	\$23.53
<i>Use will remain stable, and mix is expected to grow from greater use of more expensive products.</i>					
Insulin	\$4.14	34.04%	\$5.55	23.0%	\$6.83
<i>Use of more expensive insulins will drive cost increases.</i>					

Table 11 continued on the following page.

% EST. CHANGE	2004 EST. \$PMPY	% EST. CHANGE	2005 EST. \$PMPY	% EST. CHANGE	2006 EST. \$PMPY	% EST. CHANGE	2007 EST. \$PMPY
18.4%	\$73.18	19.8%	\$87.58	18.2%	\$103.58	16.6%	\$120.78
20.5%	\$67.85	21.5%	\$82.44	19.5%	\$98.51	17.5%	\$115.75
-3.0%	\$5.25	-2.0%	\$5.15	-2.0%	\$5.04	-2.6%	\$4.94
18.3%	\$117.55	18.1%	\$138.77	17.8%	\$162.33	16.6%	\$188.28
12.5%	\$72.86	16.5%	\$82.36	14.5%	\$94.53	13.5%	\$107.29
25.5%	\$22.46	25.5%	\$28.19	25.5%	\$35.37	25.5%	\$44.39
7.5%	\$7.51	7.5%	\$8.07	7.5%	\$8.68	7.5%	\$9.35
21.5%	\$18.33	20.5%	\$12.44	20.5%	\$14.99	20.5%	\$18.27
18.5%	\$6.40	17.5%	\$7.52	16.5%	\$8.76	16.5%	\$10.21
12.6%	\$72.54	12.6%	\$82.42	14.4%	\$94.26	14.7%	\$108.87
20.5%	\$75.18	19.5%	\$89.84	18.5%	\$106.46	17.5%	\$125.08
16.0%	\$40.60	17.5%	\$47.70	18.5%	\$56.53	18.5%	\$66.98
3.5%	\$14.70	3.5%	\$15.22	3.5%	\$15.75	3.3%	\$16.30
14.5%	\$13.85	14.0%	\$15.80	13.5%	\$17.93	13.5%	\$20.35
8.5%	\$3.37	9.5%	\$3.76	9.5%	\$4.05	9.5%	\$4.43
14.9%	\$68.31	14.6%	\$78.38	14.5%	\$89.65	14.2%	\$102.51
6.5%	\$12.06	6.5%	\$12.84	7.5%	\$13.80	8.5%	\$14.95
15.5%	\$23.78	15.5%	\$27.46	15.5%	\$31.72	15.5%	\$36.64
18.5%	\$21.23	17.5%	\$24.96	16.5%	\$29.36	15.5%	\$33.57
16.5%	\$11.25	16.0%	\$13.04	15.5%	\$15.07	15.0%	\$17.35
18.3%	\$36.83	17.8%	\$42.86	17.6%	\$49.94	17.6%	\$58.73
17.5%	\$27.76	17.5%	\$32.62	17.5%	\$38.33	17.5%	\$45.84
21.0%	\$3.27	19.0%	\$9.84	18.0%	\$11.61	18.0%	\$13.70

2002 Drug Trend Report

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Table 11:  
2001-2002 Summary and 2003-2007 Forecast for Major Therapy Classes

THERAPY CLASS	2001 \$PMPT	% CHANGE	2002 \$PMPT	% EST. CHANGE	2003 EST. \$PMPT
<b>Respiratory</b>	\$51.71	28.6%	\$62.85	18.3%	\$71.57
Anesthetics	\$18.13	22.8%	\$22.27	19.6%	\$26.51
<i>Utilization will continue to grow and the use of more expensive products (Singulair®, Pulmicort® and Advair Diskus®) will lead to double-digit growth.</i>					
Antihistamines	\$17.89	21.2%	\$21.69	16.0%	\$25.16
<i>Utilization and mix difficult to project given uncertainty over plan sponsor DTC coverage rules.</i>					
Cough/Cold	\$8.53	13.6%	\$9.69	10.5%	\$10.71
<i>Utilization and mix difficult to project given uncertainty over plan sponsor DTC coverage rules.</i>					
Decongestants/Nasal Steroids	\$7.15	17.4%	\$8.40	9.5%	\$9.20
<i>Growth will moderate with few expected new products.</i>					
<b>Dermatologicals</b>	\$14.37	4.1%	\$15.05	11.8%	\$16.71
<i>Price increases will drive class costs.</i>					
<b>Antivirals</b>	\$18.52	43.1%	\$15.08	21.7%	\$18.32
HIV	\$5.15	5.82%	\$5.45	9.5%	\$5.96
<i>New, expensive drug introductions in 2003 will increase per prescription costs.</i>					
Hepatitis	\$3.14	15.06%	\$3.61	12.0%	\$4.04
<i>Modest growth will continue.</i>					
Hepatitis	\$2.24	168.16%	\$6.00	38.5%	\$8.31
<i>Utilization growth will continue but will moderate over time.</i>					
<b>Women's Health</b>	\$32.33	12.8%	\$36.51	13.5%	\$41.45
Estrogens	\$11.52	-5.3%	\$11.04	-0.5%	\$10.99
<i>Utilization will continue to decline in 2003 and then will remain relatively stable.</i>					
Oral Contraceptives	\$8.91	19.6%	\$10.55	13.5%	\$12.09
<i>Cost growth primarily driven by expected wider coverage of OCs by plan sponsors.</i>					
Misc. Endocrine	\$11.83	25.6%	\$14.82	24.0%	\$18.39
<i>The aging of the population, massive undertreatment of osteoporosis in women and men, and fear of using estrogens will lead to substantial utilization growth.</i>					
<b>Anti-infectives</b>	\$27.35	2.1%	\$28.11	5.9%	\$29.76
Macrolides	\$7.52	-0.4%	\$7.48	1.0%	\$7.56
<i>Price increases will be primary factor in overall class cost growth.</i>					
Cephalosporins	\$5.55	0.4%	\$5.57	-0.5%	\$5.54
<i>Class dominated by generics and use expected to decline.</i>					
Penicillins	\$7.21	2.3%	\$7.36	5.5%	\$7.76
<i>Class dominated by generics and use expected to decline.</i>					
Quinolones	\$7.08	8.8%	\$7.70	15.5%	\$8.69
<i>Class costs will escalate as utilization increases substantially.</i>					
<b>Subtotal</b>	\$408.46	17.6%	\$488.48	15.5%	\$554.85
<b>Other</b>	\$85.71	22.6%	\$105.12	15.5%	\$121.59
<b>Total</b>	\$494.17		\$593.60		\$676.44

% EST. CHANGE	2004 EST. \$PMPT	% EST. CHANGE	2005 EST. \$PMPT	% EST. CHANGE	2006 EST. \$PMPT	% EST. CHANGE	2007 EST. \$PMPT
13.5%	\$81.24	12.6%	\$81.44	12.3%	\$102.69	11.6%	\$114.64
17.5%	\$31.15	15.5%	\$35.97	15.5%	\$41.55	13.5%	\$47.16
14.5%	\$28.81	13.5%	\$32.70	12.5%	\$36.79	12.5%	\$41.38
6.5%	\$11.40	6.5%	\$12.14	6.5%	\$12.53	6.5%	\$13.77
7.5%	\$9.59	7.5%	\$10.63	7.5%	\$11.43	7.5%	\$12.28
11.8%	\$18.55	11.8%	\$20.59	11.8%	\$22.85	11.0%	\$25.37
20.8%	\$22.14	18.5%	\$26.24	15.8%	\$38.34	12.9%	\$34.25
9.5%	\$6.53	8.5%	\$7.08	7.5%	\$7.52	6.5%	\$8.11
11.5%	\$4.51	11.0%	\$5.00	10.5%	\$5.53	10.5%	\$6.11
33.5%	\$11.10	27.5%	\$14.15	21.5%	\$17.19	16.5%	\$20.03
16.2%	\$47.73	16.5%	\$55.69	17.8%	\$65.49	18.6%	\$77.87
5.0%	\$11.31	4.6%	\$11.75	5.0%	\$12.35	6.0%	\$13.29
13.5%	\$13.72	13.5%	\$15.57	13.5%	\$17.68	13.5%	\$20.06
23.5%	\$22.70	24.5%	\$28.26	23.5%	\$35.47	25.5%	\$44.51
5.8%	\$31.49	6.4%	\$33.51	7.1%	\$35.88	7.5%	\$38.55
1.0%	\$7.63	1.0%	\$7.71	1.0%	\$7.79	1.0%	\$7.87
0.5%	\$5.57	0.5%	\$5.60	0.5%	\$5.63	0.5%	\$5.66
5.5%	\$8.19	5.5%	\$8.64	5.5%	\$9.12	5.5%	\$9.62
12.5%	\$10.09	14.5%	\$11.55	15.5%	\$13.34	15.5%	\$15.41
16.8%	\$643.86	16.8%	\$746.76	15.6%	\$863.45	15.2%	\$994.81
16.0%	\$140.86	16.0%	\$163.37	15.6%	\$188.90	15.2%	\$217.64



## New Products Expected to Come to Market Between 2003 and 2007

### Gastrointestinal (GI)

Biologic products will begin to make a greater impact in the treatment of Crohn's disease.

Antegren<sup>®</sup> is a humanized monoclonal antibody designed to bind to receptors on white blood cells, altering their response to and involvement in the inflammatory process. This drug is being studied for a variety of diseases with an inflammatory component, including Crohn's disease and multiple sclerosis (MS). Humicade<sup>™</sup>, a monoclonal antibody that blocks the effects of Tumor Necrosis Factor alpha (TNF-alpha), is also under investigation for the treatment of both Crohn's disease and rheumatoid arthritis (RA). Once approved, these agents will compete with Remicade<sup>®</sup>, which is currently the only biologic agent approved for the treatment of Crohn's disease.

In 2002, the FDA approved the marketing of Zelnorm<sup>®</sup> and the re-introduction of Lotronex<sup>®</sup> for the treatment of irritable bowel syndrome (IBS). However, with approximately 50 million Americans believed to suffer from IBS, its treatment remains a relatively untapped market. Dextroglutamide and renzapride are being studied for the treatment of constipation-predominant IBS, while cilansetron is being evaluated for the treatment of the diarrhea-predominant type of the disease. The FDA may be cautious with the approval of these products following the withdrawal and eventual re-introduction of Lotronex<sup>®</sup>.

Emend<sup>®</sup> is a substance p inhibitor for the treatment of chemotherapy-induced nausea and vomiting. Clinical trials have indicated that when used in combination with other anti-emetics, Emend<sup>®</sup> may be effective for the treatment of both acute and delayed nausea and vomiting. If FDA review proceeds as planned, this drug should reach the market in 2003.

BRAND NAME	GENERIC NAME	PROPOSED USE	EXPECTED RELEASE DATE				
			2003	2004	2005	2006	2007
Antegren <sup>®</sup>	nataleumab	Crohn's disease		X			
Emend <sup>®</sup>	aprepitant	Nausea, vomiting	X				
	dextroglutamide	IBS			X		
	cilansetron	IBS				X	
	renzapride	IBS					X
Humicade <sup>™</sup>	CDP-571	Crohn's disease		X			

#### Patent Expirations:

- Zofran<sup>®</sup> 2005
- Protonix<sup>®</sup> 2006 (extension likely)

### Central Nervous System (CNS)

In 2003, three additional medications for the treatment of erectile dysfunction (ED) may enter the U.S. prescription market. Cialis<sup>®</sup> and Levitra<sup>®</sup>, oral medications that are currently under FDA review, have a mechanism of action similar to Viagra<sup>®</sup>. However, they are more selective for the phosphodiesterase 5 enzyme (which may result in fewer side effects), and they have a longer duration of action. Uprima<sup>®</sup> is a dopamine receptor agonist that is administered sublingually (under the tongue). Since it has a different mechanism of action, it has the potential to work in patients who are unresponsive to the other therapies.

The treatment of depression is another significant focus for medication development. Cymbalta<sup>®</sup> is a norepinephrine and serotonin re-uptake inhibitor for the treatment of depression and, at a different dose, for the treatment of stress urinary incontinence. Gepirone ER is a 5-HT<sub>1A</sub> agonist for the treatment of major depression and major depression with anxiety. However, the FDA is requiring additional studies to support marketing approval, delaying potential approval until at least 2004. Aprepitant is also being studied as an antidepressant, but limited efficacy data are available at this time.

The sedative/hypnotic market will see some additional growth in the upcoming years. Estorra<sup>™</sup> is under development for the treatment of transient and chronic insomnia. It is an isomer of zopiclone, a hypnotic agent available only outside of the U.S. Indiplon is a GABA agonist/non-benzodiazepine sedative/hypnotic for treatment of chronic insomnia. It is being looked at in both rapid-release and modified-release formulations to help initiate and maintain sleep.

Pregabalin is a follow-on compound to Neurontin<sup>®</sup>. It is being studied for many diseases, including epilepsy, general anxiety disorder (GAD) and neuropathic pain. Development of this drug was temporarily delayed due to concerns about carcinogenicity in animal studies.

BRAND NAME	GENERIC NAME	PROPOSED USE	EXPECTED RELEASE DATE				
			2003	2004	2005	2006	2007
Cymbalta <sup>®</sup>	duloxetine	Depression, urinary incontinence	x				
Cialis <sup>®</sup>	tadalafil	Erectile dysfunction	x				
Levitra <sup>®</sup>	vardenafil	Erectile dysfunction	x				
Uprima <sup>®</sup>	apomorphine	Erectile dysfunction	x				
	iramemine	Alzheimer's disease		x			
Zenaril <sup>®</sup>	iloperidone	Psychosis		x			
Estorra <sup>™</sup>	esopiclone	Hypnotic		x			
	pregabalin	Epilepsy, GAD, neuropathic pain			x		
	rimonabant	Obesity			x		
	gepirone ER	Depression		x			
	aprepitant	Depression			x		
	Crg-5272	Psychosis					x
	indiplon	Hypnotic			x		

#### Patent Expirations:

- Neurontin<sup>®</sup> key patent expired (ongoing litigation), competition possible 2003
- Serzone<sup>™</sup> 2003
- Levitra<sup>®</sup> 2007
- Wellbutrin SR<sup>®</sup>/Zyban<sup>®</sup> patent expired (generics awaiting appellate ruling/FDA approval)
- Paxil<sup>®</sup> 2002 (ongoing litigation)
- Ambien<sup>®</sup> 2007
- Celebra<sup>®</sup> 2004
- Zolot<sup>®</sup> 2005

2002 Drug Trend Report

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### Respiratory

Xolair<sup>®</sup> is a monoclonal antibody that binds and inhibits the effects of IgE antibodies, which are immune system proteins involved in the inflammatory process that produces many symptoms of allergic asthma. This product may be limited to the treatment of severe, refractory asthma because it likely will require a monthly injection in a clinic setting. A product with a similar mechanism of action is TNX-901, which is being developed to provide protection against reactions to unintentional peanut ingestion by people who have severe allergies to peanuts.

With initiatives to comply with the Montreal Protocol by phasing out the use of all chlorofluorocarbons (CFCs), some of the currently available metered dose inhalers used to treat asthma eventually will be removed from the market. Therefore, the additional CFC-free products under development will increase therapeutic options for people with asthma. Ciclesonide and Asmanex<sup>®</sup> are both CFC-free inhaled corticosteroids for the maintenance treatment of asthma. Spiriva<sup>®</sup> is a longer-acting version of the drug in Atrovent<sup>®</sup>. Therapy with Spiriva<sup>®</sup> would require a once-daily administration, compared to four times a day with Atrovent<sup>®</sup>.

A new class of oral medications known as phosphodiesterase 4 (PDE4) inhibitors may provide anti-inflammatory and bronchodilatory effects for the treatment of asthma and chronic obstructive pulmonary disease (COPD), including emphysema and chronic bronchitis. Leading agents in this class include Arflo<sup>®</sup> and roflumilast. Some physicians feel that these products may have only modest benefits over theophylline. However, their roles in the treatment of asthma and COPD have yet to be determined.

The non-sedating antihistamine class may see another addition in 2004, following the completion and analysis of additional safety studies for Soltara<sup>®</sup>. In March 2002, the FDA issued a "not approvable" letter for Soltara<sup>®</sup>, making its market entry date uncertain.

BRAND NAME	GENERIC NAME	PROPOSED USE	EXPECTED RELEASE DATE				
			2003	2004	2005	2006	2007
Spiriva <sup>®</sup>	tiotropium	COPD	x				
Xolair <sup>®</sup>	omalizumab	Allergic asthma	x				
Arflo <sup>®</sup>	clorazepate	Asthma, COPD		x			
Asmanex <sup>®</sup>	ciclesonide	Asthma		x			
Asmanex <sup>®</sup>	mometasone	Asthma	x				
	roflumilast	Asthma, COPD			x		
Soltara <sup>®</sup>	fexofenadine	Allergies		x			
	TNX-901	Peanut allergies				x	

#### Patent Expirations

- Flovent<sup>®</sup> 2004
- Flovent<sup>®</sup> 2004
- Allegra<sup>®</sup> 2004 (pending court ruling)
- Zyrtec<sup>®</sup> 2007
- Claritin<sup>®</sup> 2007

### Pain/Inflammation

The marketing of biologic products for the treatment of psoriasis and psoriasis-related complications will increase disease awareness, expand treatment options and eventually transform treatment of this disease into the next multi-billion dollar market. Raptiva™ is the next new biologic agent likely to receive approval for the treatment of psoriasis. However, look for the TNF inhibitors currently on the market (e.g., Enbrel®, Remicade® and Humira™) to seek approval for the treatment of psoriasis. In 2005, the growing class of TNF inhibitors will see the introduction of CDP-870, which has the added convenience of once-a-month subcutaneous administration. Other agents for the treatment of rheumatoid arthritis (RA) include Tenovil®, a natural anti-inflammatory and immune system regulator; and pralucasan, an orally active small molecule drug known as an ICE inhibitor (interleukin-1b converting enzyme inhibitor), a medication that may block the formation of key cytokines involved in the inflammation process.

Two additional COX-2 inhibitors will likely compete in this multi-billion dollar market in 2004. Submission of the new drug application (NDA) for Arcoxia™ with data to support its use in ankylosing spondylitis (RA of the spine) is anticipated in mid-2003, placing its final approval sometime in 2004. The NDA for Prexige® was submitted to the FDA in 2002, but an additional clinical trial will be required to support approval, delaying final approval until at least 2004. It is unclear if these agents will offer any clinical advantages in the COX-2 inhibitor class, or only compete for a share of the market.

Antegren®, a humanized monoclonal antibody, is one of the first in a new class of alpha 4 integrin inhibitors that prevent the migration of inflammatory cells from blood vessels to sites of inflammation. Antegren® is being studied for the treatment of inflammatory diseases, including Crohn's disease and multiple sclerosis (MS).

BRAND NAME	GENERIC NAME	PROPOSED USE	EXPECTED RELEASE DATE				
			2003	2004	2005	2006	2007
Raptiva®	efalizumab	Psoriasis	x				
Prexige®	lumiracoxib	Arthritis, pain		x			
	CDP-870	RA			x		
Tenovil®	E-10	RA			x		
Antegren®	marizumab	MS		x			
Arcoxia™	etoricoxib	Arthritis, pain		x			
	pralucasan	RA				x	
Humira™	adalimumab	Arthritis			x		

#### Patent Expirations

- Duragesic® 2006
- OxyContin® 2007

### Cardiovascular

As the patents on several key cholesterol-lowering products begin to approach expiration, manufacturers are working to develop novel therapies for modifying cholesterol levels (raising HDL or lowering total cholesterol, LDL and triglycerides). The next entrants to the "statin" market likely will be Crestor<sup>®</sup> in late 2003, followed by pitavastatin in 2006. Avasimibe is an ACAT (acyl-coenzyme A:cholesterol acyltransferase) inhibitor that may prevent the progression of atherosclerosis as well as lower cholesterol. CP-529,414 is a cholesterol ester transfer protein (CETP) inhibitor to be used in combination with Lipitor<sup>®</sup> to elevate HDL cholesterol and lower LDL cholesterol.

Lercanidipine is a calcium blocker anticipated to compete with Norvasc<sup>®</sup> for the treatment of hypertension. Although an NDA for lercanidipine was submitted in 2001, the FDA is requiring additional clinical trials prior to granting full approval.

Exanta<sup>™</sup> is a novel, orally-administered thrombin inhibitor for the prevention of venous thromboembolisms in orthopedic surgery. If approved, this drug is likely to compete with the low-molecular-weight heparins and Coumadin<sup>®</sup>. Dronedarone is an antiarrhythmic medication similar to amiodarone. However, a recent study of this drug was discontinued following an interim analysis showing an excess risk of death in the treatment group. An in-depth analysis of the results will be required before a new study protocol is considered.

Conivaptan is a vasopressin (V1 and V2) receptor antagonist for treatment of hyponatremia (sodium deficiency) and CHF. Fasidotril, a vasopectidase inhibitor, is another drug being studied for the treatment of congestive heart failure (CHF) and hypertension. If development of this drug continues as planned, it will help address the increased incidence of angioedema experienced with other vasopectidase inhibitors (e.g., Vanlev<sup>™</sup>).

BRAND NAME	GENERIC NAME	PROPOSED USE	EXPECTED RELEASE DATE				
			2003	2004	2005	2006	2007
Crestor <sup>®</sup>	rosuvastatin	Dyslipidemia	X				
Exanta <sup>™</sup>	ximelagatran	Anticoagulant		X			
	lercanidipine	Hypertension				X	
	dronedarone	Arrhythmia			X		
	pitavastatin	Dyslipidemia				X	
	avasimibe	Dyslipidemia, atherosclerosis				X	
	CP-529,414	Dyslipidemia			X		
	conivaptan	Hyponatremia, CHF			X		
	fasidotril	Hypertension, CHF					X

#### Patent Expirations

- Accupril<sup>®</sup> 2003
- Monopril<sup>®</sup> 2003
- Lotensin<sup>®</sup> 2004
- Allace<sup>®</sup> 2005
- Pravachol<sup>®</sup> 2005
- Zocor<sup>®</sup> 2006
- Norvasc<sup>®</sup> 2007
- Coreg<sup>®</sup> 2007

### Women's Health

Seasonale<sup>®</sup> is likely to enter the market in 2003. This novel oral contraceptive is taken continuously for 84 days, followed by a week of placebo to allow for a menstrual period. This would decrease the number of periods from 13 to 4 per year for women taking the drug. Physicians have been prescribing monophasic oral contraceptives in a similar manner for the treatment of endometriosis, severe dysmenorrhea and migraines that worsen during the menstrual period.

With the recent FDA-recommended labeling changes for estrogen-containing hormone replacement therapies (HRT), the use of non-estrogen products for the treatment and prevention of postmenopausal osteoporosis is likely to increase. Bazedoxifene and lasofoxifene are estrogen-receptor modulators under study for the prevention of postmenopausal osteoporosis. Bonviva<sup>®</sup> likely will be the next agent introduced to the bisphosphonate market. However, a once-weekly Bonviva<sup>®</sup> formulation probably will be required to compete with the market leaders. Xyvion<sup>®</sup> is a product that possesses weak estrogenic, progestogenic and androgenic properties. Its continued development may be questionable, due to the recent FDA-requested changes to estrogen products for use as HRT.

BRAND NAME	GENERIC NAME	PROPOSED USE	EXPECTED RELEASE DATE				
			2003	2004	2005	2006	2007
Seasonale <sup>®</sup>	ethinyl estradiol/ levonorgestrel	Oral contraceptive	x				
Bonviva <sup>®</sup>	ibandronate	Osteoporosis			x		
Xyvion <sup>®</sup>	binchone	HRT				x	
	bazedoxifene	Osteoporosis, HRT				x	
	lasofoxifene	Osteoporosis, HRT			x		

#### Patent Expirations

- Nolvadex<sup>®</sup> 2003
- Ciba Ti-Cycles<sup>®</sup> 2003
- Ortho-Mevion<sup>®</sup> 1/1/2003
- Fesatex<sup>®</sup> 2003 (patent challenges pending)

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### Anti-Infectives

Fuzeon™, approved in March 2003, is the first drug in a new class of HIV medications. Known as viral fusion inhibitors, this class of drugs prevents HIV from binding to and "fusing" with healthy T-cells, preventing the healthy cells from becoming infected. Therapy with this drug will require a subcutaneous injection twice daily, and it will be used in combination with oral medications for HIV treatment. Also in development are other drugs with mechanisms of action similar to products currently available for the treatment of HIV. They include capravirine, atazanavir and fosamprenavir. These drugs may provide incremental benefits over the current drugs, but their true place in therapy has yet to be determined.

Ketolides are a new, emerging class of antibiotic drugs. Derivatives of macrolide antibiotics (e.g., erythromycin, clarithromycin), they have been shown to be effective against some strains of macrolide-resistant bacteria. With approval expected in 2003, Ketek® likely will be the first ketolide introduced in the U.S. Other antibiotics in development include garenoxacin, a broad spectrum quinolone; and oritavancin, a glycopeptide for the treatment of gram positive infections.

FluMist™ is an intranasal flu vaccine for the prevention of respiratory influenza. As with other influenza vaccines, it will be reformulated annually to reflect the currently circulating influenza A and B viruses. Initially, it likely will be limited for use in individuals from 5 to 49 years of age. A second intranasal influenza vaccine, FluMisture™, is currently in early clinical trials.

A couple of antifungal agents are in the near-term pipeline. Ravuconazole is a broad-spectrum antifungal with activity against most of the fungi that are responsible for severe infections in patients with or without a healthy immune system (e.g., aspergillosis, mucosal candidiasis, endemic mycosis and onychomycosis). The use of posaconazole, however, likely will be limited to severe infections in individuals with a compromised immune system (e.g., aspergillosis).

BRAND NAME	GENERIC NAME	PROPOSED USE	EXPECTED RELEASE DATE				
			2003	2004	2005	2006	2007
Fuzeon™	enfuvirtide	HIV	x				
FluMist™	influenza vaccine intranasal	Influenza vaccine	x				
FluMisture™	influenza vaccine intranasal	Influenza vaccine				x	
Ketek®	telithromycin	Antibiotic	x				
	garenoxacin	Antibiotic		x			
	atazanavir	HIV	x				
	fosamprenavir	HIV	x				
Noxafil®	posaconazole	Antifungal		x			
	oritavancin	Antibiotic			x		
	capravirine	HIV				x	
	ravuconazole	Antifungal					x

#### Patent Expirations

• Siro® 2003	• Diflucan® 2004	• Zithromax® 2005	• Lenix® 2007
• Rebetol® 2003	• Biaxin® 2005	• Celzir® 2005	

### Diabetes

A new class of injectable agents for the treatment of diabetes is beginning to emerge. Modeled after natural body chemicals known as glucagon-like peptide (GLP)-1, the new agents are being studied for their roles in regulating blood glucose. The furthest in development is Symlin<sup>®</sup>, followed by exendin-4 and NN-2211.

Insulin glulisine (HMR-1964) is a rapid-acting insulin analog similar to Novolog<sup>®</sup> and Humalog<sup>®</sup>. Insulin detemir is a long-acting basal insulin that provides less day-to-day variation in insulin levels than experienced with NPH. It will compete primarily with Lantus<sup>®</sup>. The development of the inhaled insulin, Exubera<sup>®</sup> (dry powder insulin for inhalation), has been delayed significantly from its original projected timelines due to concerns about its long-term effects on pulmonary function.

LAF-237 is a dipeptidyl peptidase (DPP) IV inhibitor for treatment of type 2 diabetes. Initial findings from a study in patients with type 2 diabetes show that it may improve glucose tolerance and insulin response to oral glucose in patients with type 2 diabetes. Glitazones in development include balaglitazone, AZ-242 and KRP-297.

Diabetes care includes not only the maintenance of blood glucose but also the management of complications associated with the disease. Ruboxistaurin (formerly known as LY333531) is a protein kinase C beta inhibitor being developed for the treatment of diabetic neuropathy, proliferative retinopathy and macular edema. Setodexide is a heparin-type molecule for treatment of diabetic nephropathy. Pregabalin, the follow-on to Neurontin<sup>®</sup>, is also being studied for the treatment of diabetic neuropathy.

BRAND NAME	GENERIC NAME	PROPOSED USE	EXPECTED RELEASE DATE				
			2003	2004	2005	2006	2007
Symlin <sup>®</sup>	pramlintide	Glucose regulation	X				
Exubera <sup>®</sup>	inhaled insulin	Diabetes		X			
	ruboxistaurin (LY333531)	Diabetes complications				X	
	balaglitazone	Oral antidiabetic				X	
	exendin-4 (AC2993)	Glucose regulation			X		
	pregabalin	Diabetic neuropathic pain			X		
	NN-2211	Glucose regulation				X	
	insulin glulisine	Insulin analog			X		
	insulin detemir	Insulin analog	X				
	setodexide	Diabetes complications			X		
	KRP-297	Oral antidiabetic					X
	LAF-237	Oral antidiabetic				X	

Patent Expirations

- Glucophage<sup>®</sup> XR 2003
- Glucovance<sup>®</sup> 2004
- Amaryl<sup>®</sup> 2005
- Actos<sup>®</sup> 2006



NOTES

Appendix B	Appendix A	Actions	Specialty Inspectables	COST FORECAST	Trends in Expenditures	Introduction	Preface	Table of Contents
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*Specialty  
Injectables*

DRUG TRENDS

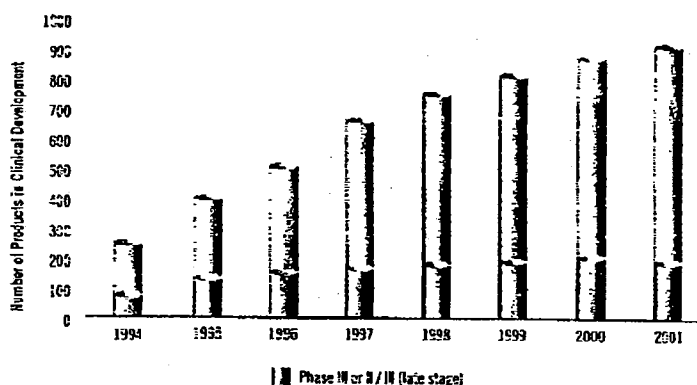
2002 Report

## The Growing Costs of Specialty Injectable Drug Products

Each year, more people use specialty injectable drugs as part of their medication therapy. In 2002, more people received specialty injectable products through their pharmacy benefits. This trend was clearly evident in Express Scripts' specialty-care pharmacy, which dispensed 90 percent more prescriptions in 2002 than in 2001.

U.S. revenues for the specialty pharmacy market, estimated at \$22 billion in 2001, are expected to increase by 20 percent annually.<sup>31</sup> The expanding biotechnology industry is a significant driving force behind this growth. In 2001, over 900 products targeting more than 200 diseases were making their way through biotechnology drug company pipelines (see Figure 10).

Figure 10  
Biotechnology Pipelines



Source: Goldman Sachs, Healthcare: Biotechnology, January 14, 2001; Page 8

Another factor driving growth of the injectable market is the lack of generic products. Although the FDA has an established process for approving generic equivalents of traditional drugs, the agency currently has no comparable process for allowing generic versions of biotech drugs to come to market.

With the typical injectable drug costing well over \$1,000 per month, payers recognize the impact that specialty injectables can have on both medical and pharmacy benefits. The first step in addressing specialty drug cost is to establish a clear definition for this category. Currently, typical inclusion criteria include the annual drug cost, whether the product is injectable or infused, and whether it is administered in the home or a physician's office. Some plans also consider high-cost oral products, such as Triciclovir or Gleevec<sup>®</sup>, as specialty drugs.

31. Ransom J. Rettig T. Specialty Drug Distribution. Raymond James and Associates, July 15, 2002. Available at: <http://www.rjresearch.com/DRUG071602RFT.PDF>. Accessed March 25, 2003

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To manage the specialty cost effectively, a plan sponsor must consider drugs covered under both pharmacy and medical benefits. The medical benefit is of particular concern because of the unique coding structure used for medical claims. Drug-specific data is rarely available in medical claims; consequently, it is difficult for a plan to measure the drug spend or determine for which drugs they are paying. Many plans have begun moving these drugs to the pharmacy benefit, in part to determine their specialty drug cost. Others have created a new benefit called an "Injectable" benefit. Finally, others are looking for technological solutions to incorporate medical claims data and drug-specific information.

Today, the most common method of addressing the costs of specialty drugs is through discounted pricing via specialty pharmacies. These pharmacies often offer discounts in return for some promise of increased volume. Plans, on the other hand, must limit their members' choices in order to steer them to these providers. Specialty pharmacies frequently offer additional patient support through education and high-touch customer service. Specialty pharmacies have the ability to bill both pharmacy and medical benefits, yet plans struggle to consolidate the data across their network to measure total specialty cost.

Formularies have proven to be an effective way for plans to lower oral drug costs. Except in the class of growth hormones, however, only a few therapeutic substitutions now exist in the specialty drug category from which to build formularies and leverage manufacturer discounts. The drug pipeline shows several upcoming opportunities for competition to existing drugs, however. Plans should actively monitor these developing drugs in preparation for adopting specialty formularies.

Clinical programs, such as prior authorization and step therapy, can affect utilization for some specialty drugs. Drug therapies for RA, MS and hepatitis C all are candidates for these types of programs. Additionally, some patients may respond to disease management programs.

Increasingly, plans are looking to pharmacy benefit managers (PBMs) to help manage the specialty drug cost. PBMs have the ability to build networks of specialty pharmacies and leverage discounts. Additionally, PBMs can offer efficient, cost-effective mail service for certain specialty drugs. Overall, PBMs have proven tools and methods to lower plan costs. Finally, as PBMs address the issue of medical claims management, they will be in a position to integrate specialty drug data across both benefits, allowing for a complete management solution.

The following sections provide an overview of the top therapeutic classes that currently drive the injectable drug market. One notable exception is a general overview of cancer therapies, which contribute significantly to healthcare costs. While certain therapeutic classes related to cancer treatment can be found in this section of the Report, a more detailed discussion of cancer and its treatments can be found in Appendix A. It is important to note that the products mentioned in this section may be covered under either the medical or the pharmacy benefit, and in some cases, both.

### Fertility Regulators

#### Primary Use: Infertility

Infertility is defined by the World Health Organization as the inability of a couple to achieve conception or bring a pregnancy to term after one year or more of regular, unprotected sexual intercourse. Primary infertility is the inability to conceive a first child and secondary infertility is the inability to conceive a second or subsequent child. One out of 10 couples worldwide experience primary or secondary infertility.<sup>32</sup> Infertility therapy is now highly successful, with pregnancy rates obtained with most treatment comparable to natural pregnancy rates.

Current drugs to treat infertility include chorionic gonadotropin (hCG), follicle-stimulating hormone (FSH), and luteinizing hormone (LH). Each of these drugs plays a specific role in the reproductive cycle. FSH stimulates the development of follicles in the ovaries, which ultimately lead to fully developed eggs. FSH is typically given with LH, which is responsible for final maturation of the developing egg; hCG triggers ovulation, so one of these products is given after FSH and LH have had time to work. Another class of products known as gonadotropin antagonists is used to control the ovulation cycle, which is important when exact timing is necessary for other infertility therapies.

Infertility treatments can be either human-derived or recombinant. Human-derived products are made from the urine of postmenopausal women, while recombinant products are produced using DNA technology. Most of the medications are self-injectable in nature. The following table lists some of the significant infertility products.

Table 12  
Selected Infertility Products

DRUG NAME	PRODUCT TYPE	METHOD OF ADMINISTRATION
Gonal-F <sup>®</sup>	Recombinant FSH	Subcutaneous
Follistim <sup>®</sup>	Recombinant FSH	Subcutaneous
Pergonal <sup>®</sup>	Human-derived FSH/LH	Intramuscular
Reprogen <sup>®</sup>	Human-derived FSH/LH	Subcutaneous
Lupron <sup>®</sup>	Gonadotropin antagonist	Intramuscular
Qudrel <sup>®</sup>	Recombinant hCG	Subcutaneous
Antagon <sup>®</sup>	Gonadotropin antagonist	Subcutaneous
Brevelle <sup>®</sup>	Human-derived FSH	Subcutaneous
Carisbide <sup>®</sup>	Gonadotropin antagonist	Subcutaneous

**Pipeline:** The pipeline for infertility drugs is relatively quiet. Most activity involves making existing products easier to take. The manufacturer of Gonal-F<sup>®</sup> is developing a microencapsulated form of the drug that is designed to decrease the frequency of injections. Other companies continue to find ways to further purify their compounds, thereby reducing the risk of adverse reactions. Oral versions of these products are years away. Luveris<sup>®</sup>, which contains FSH and luteinizing hormone-releasing hormone (LHRH), is currently under review at the FDA.

<sup>32</sup> Department of Reproductive Health and Research (RHR) World Health Organization, Infertility, October 2002. Available at: <http://www.who.int/reproductive-health/infertility/index.htm>. Accessed March 25, 2003.

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### **Beta-Interferons**

#### **Primary Use: Multiple Sclerosis**

Multiple sclerosis (MS) is a progressive disease of the central nervous system. It is an autoimmune disease in which tissues surrounding the nerves of the body are damaged. This results in an inability of the nerves to communicate with one another, and leads to symptoms such as tremor, loss of balance and visual disturbances. MS has no cure.

There are four major types of MS: Relapsing-Remitting, Secondary-Progressive, Primary-Progressive and Progressive-Relapsing. Relapsing-Remitting MS is the most common form, occurring in approximately 75 percent of patients. This type of MS is characterized by intermittent attacks, or relapses, of MS symptoms followed by periods of near-normal functioning. About half of the patients with Relapsing-Remitting MS progress to Secondary-Progressive MS, in which the symptoms of MS may wax and wane, but the disease progresses overall. In contrast, Primary-Progressive MS patients experience a slow but continuous worsening of MS symptoms without periods of remission. The final type of MS, Progressive-Relapsing, is noted by immediate disease progression with occasional periods of remission.

The current market basket of drugs used to treat MS consists of Copaxone<sup>®</sup> and Novantrone<sup>®</sup> as well as the beta-interferons. In 1993, Betaseron<sup>®</sup> was the first beta-interferon approved, followed in 1996 by Avonex<sup>®</sup> and in 2002 by Rebif<sup>®</sup>. All of the beta-interferons are indicated for the treatment of Relapsing-Remitting MS. Avonex<sup>®</sup> is administered as a once-weekly intramuscular injection, while Betaseron<sup>®</sup> is administered every other day and Rebif<sup>®</sup> three times per week. In 1997, Copaxone<sup>®</sup> was introduced to the market. Copaxone<sup>®</sup> is not an interferon but instead works by blocking nerve-damaging cells. Novantrone<sup>®</sup> has been on the market for many years as an anti-cancer drug, and in 2000 it received approval for MS. Due to its side effect profile and monitoring requirements, it is typically reserved for more severe cases.

**Pipeline:** Perhaps the most promising compound in the pipeline for MS is Antegren<sup>®</sup> (natalizumab). Antegren<sup>®</sup> is the first monoclonal antibody being developed for MS; it provides a different mechanism of action than currently available therapies. Because of its unique mechanism of action, Antegren<sup>®</sup> can be used for patients who have not responded to other MS therapies, and it can be used in combination with a currently available treatment. An oral version of Copaxone<sup>®</sup> is under development, but initial studies did not show a treatment benefit. Other drugs in development focus on the immune system and the source of inflammation, but they will not reach the market for a few years.

### **Interleukins**

#### **Primary Uses: Selected Cancers and Low Platelets in Cancer Patients**

Interleukins are a group of proteins that play an important role in regulating some of the body's activities. Found within body cells, interleukins and other similar proteins are part of a family of chemicals called cytokines, which function as one of the body's messenger services. Cytokines carry important information between cells, instructing the cells to perform a certain function. For example, one cytokine may tell the body to increase the amount of cancer cells in a tumor, while another may be designed to decrease the number of platelets being manufactured by the body.

At least 27 different forms of interleukin have been identified in the body. They are named by number (interleukin-1, interleukin-2, etc.) and often abbreviated as IL-1, IL-2, and so on.

Drug therapy using Interleukins is achieved either by increasing the amount of interleukins circulating in the body or by blocking their effects. The first interleukin product, Proleukin® (IL-2) was approved by the FDA in 1992 for the treatment of kidney cancer. Proleukin® works by assisting the body's own interleukins in attacking and killing cancer cells. It is typically administered in a hospital setting because of potential side effects. The second interleukin, Neumega® (IL-11) is approved for patients with low platelet counts following chemotherapy. Neumega® directly stimulates the development of platelets. It can be self-injected once daily until platelet levels return to normal, a process that usually takes 21 days or less. The third interleukin drug approved by the FDA does not enhance interleukin activity but instead prevents it. Kineret™ blocks the effects of interleukin-1, which is one of the prime causes of inflammation in rheumatoid arthritis patients. It is given as a self-injection on a daily basis. Therapy with Kineret™, unlike Proleukin® and Neumega®, is chronic in nature.

**Pipeline:** Significant research is taking place in the field of interleukins. Because there are so many potential sites of action (27 or more), identifying potential drug targets is important. Currently, at least 11 interleukin subtypes are under study for potential drug targeting. Diseases potentially treatable with these products include asthma, Crohn's disease, MS, lupus, psoriasis, dermatitis and many different forms of cancer. Despite this significant activity, no new interleukin drugs are expected on the market in the immediate future. Prestara™, a hormone-based drug with interleukin activity (but not a true interleukin), is a future candidate for approval.

### **Alfa-interferons**

#### **Primary Use: Hepatitis C**

Like interleukins, interferons are natural proteins produced by the human body. They assist the body's other defenses in fighting off invading cells that can carry disease. Although interferons were discovered in the 1950s, the first was not approved for use until 1986. Because of their relatively non-specific effects, interferons are used in a wide variety of disease states. Three different forms of interferon are on the market today, and while they are all interferon molecules, they differ in their specific mechanisms of action and response to disease. Alfa-interferons, the first interferons introduced, are used for different types of cancer, hepatitis and genital warts. In 1993, the first beta-interferon was approved for the treatment of MS. A gamma-interferon, Actimmune®, was approved in 1990 for the treatment of a rare immune deficiency called chronic granulomatous disease. The remainder of this section will focus on alfa-interferon therapies.

The current alfa-interferon market consists of several products, although two newer products are receiving the most attention. The first alfa-interferons, Intron® A and Roferon®-A, were approved in 1986 for treating patients with hairy cell leukemia, a form of cancer. In subsequent years these products received additional indications for the treatment of hepatitis C and Kaposi's sarcoma, a cancer fairly common among AIDS patients. Intron® A and Roferon®-A are similar products and both are produced using recombinant DNA technology. In 1989, the interferon Aferon N® was approved for the treatment of genital warts. Aferon N® differs from Intron® A and Roferon®-A in

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that it is produced using human white blood cells rather than by recombinant DNA technology. A fourth alpha-interferon, Ingerferon<sup>®</sup>, was approved in 1997 for the treatment of hepatitis C. Ingerferon<sup>®</sup> differs from the aforementioned products in its chemical structure, so it is not a true alpha-interferon but it is very similar.

While interferons were used modestly with some success in different patient groups, their use grew dramatically with the approval of Rebetrone<sup>™</sup> in 1998. Rebetrone<sup>™</sup> combines Intron<sup>®</sup> A with the oral antiviral drug ribavirin for the treatment of hepatitis C. It was an immediate success due to the improved response rates seen with this combination therapy. The hepatitis C market surged in the following years as more patients were diagnosed and started on therapy. In 2001, a new form of Intron<sup>®</sup> A was introduced. Called PEG-Intron<sup>®</sup>, it offers similar effectiveness to Intron<sup>®</sup> but fewer injections per week (one versus three). PEG-Intron<sup>®</sup> was joined by a competing product, Pegasys<sup>®</sup>, in 2002. Pegasys<sup>®</sup> is also administered once weekly.

**Pipeline:** The interferon pipeline largely focuses on expanding the uses of existing drugs rather than developing new drugs. For example, alpha-interferons are being studied for the treatment of several cancers, including melanoma, non-Hodgkin's lymphoma and chronic myelogenous leukemia (CML). Research with gamma-interferon focuses on cystic fibrosis, asthma and ovarian cancer. A new class of interferons, the omega-interferons, is in early stages of development for hepatitis C and cirrhosis. One specific omega-interferon is being designed to target the liver, which may lessen the side effects seen with other interferons. Perhaps the most unique drugs in development are interferon antagonists. These anti-interferon drugs are expected to be tested for diseases, such as Crohn's disease and psoriasis, in which the overexpression of interferons is detrimental.

### Heparins

#### Primary Use: Prevention of Blood Clots

Heparin products are also known as anticoagulants. Their primary role is the prevention and treatment of deep vein thrombosis (DVT) and pulmonary embolism (PE). DVT occurs in the deep veins of the body, most often in the veins of the legs. It can be caused by a variety of conditions, such as inactivity, obesity or trauma. Each of these conditions includes periods of decreased venous blood flow. When this occurs, the body starts to initiate its coagulation process, which ultimately leads to the formation of a blood clot. Most often a blood clot stays in the location where it is formed, such as the leg, resulting in localized pain and discomfort. However, sometimes a blood clot breaks loose from its location and enters the general circulation. If the clot reaches the arteries of the lung, it may result in a PE, which can be fatal.

Heparin is the standard of care for acute treatment of DVT and PE. The effects of heparin have been known for almost a century. Heparin binds to a specific mediator in the coagulation process and works quickly to dissolve blood clots. It is usually given by intravenous infusion in a hospital setting. Heparin is also widely used for the prevention of DVT, as a subcutaneous injection. However, heparin therapy requires intense monitoring, so opportunities for patients to self-inject heparin remained limited until the 1990s, when heparin therapy was enhanced by the approval of Lovenox<sup>®</sup>, the first low-molecular-weight heparin. Lovenox<sup>®</sup> and subsequent similar products



contain a smaller piece of the heparin molecule, and they are administered as self-injections. Low-molecular-weight heparins are equally as effective as heparin for the treatment of DVT and PE, and they provide a safety benefit over regular heparin because typically monitoring is not required. Two products, Lovenox<sup>®</sup> and Innohep<sup>®</sup>, are approved for the prevention and treatment of DVT, while two additional products, Fragmin<sup>®</sup> and Arixtra<sup>®</sup>, are approved for the prevention of DVT. Technically, Arixtra<sup>®</sup> is not a heparin, but it works similarly to the low-molecular-weight heparin products.

**Pipeline:** Currently, research focuses on oral products that could eventually replace the injections now required for the treatment of DVT. Warfarin is a widely available oral anticoagulant, but it takes a few days to work, which is why heparin and warfarin are given together to many patients who have experienced DVT. The product closest to market is Exanta<sup>™</sup>, which is a direct thrombin inhibitor being studied for both prevention and treatment of DVT. Other products in the pipeline are designed to target specific factors that cause coagulation, and several companies are designing oral versions of heparin itself.

#### **LHRH Analogs**

##### **Primary Uses: Endometriosis and Prostate Cancer**

LHRH is an abbreviation for luteinizing hormone-releasing hormone, and an LHRH analog is a drug that mimics the effect of LHRH in the body. Given on a short-term basis, LHRH increases the levels of follicle-stimulating hormone (FSH) and luteinizing hormone (LH), which are the hormones responsible for increasing the levels of testosterone (in males) and estrogen (in females). As a result, LHRH analogs are often used as part of an infertility regimen in women. However, if LHRH is given on a more chronic basis, levels of FSH and LH are reduced, resulting in low levels of testosterone or estrogen. Conditions in which low levels of FSH and LH are desirable include prostate cancer, endometriosis and central precocious puberty. Because LHRH analogs decrease the levels of sex hormones in the body, they have the effects of chemical castration in males and cessation of menstruation in females. These effects are reversible upon discontinuation of therapy.

The most commonly used LHRH analog is Lupron<sup>®</sup>. Lupron<sup>®</sup> comes in many different formulations, including a subcutaneous injection and several long-acting, or depot, formulations that can be given in intervals of up to 4 months. An implanted version, called Viadur<sup>®</sup>, is active for one year. A second LHRH analog, Zoladex<sup>®</sup>, is also available as a subcutaneous injection in 1-month or 3-month depot formulations. Zoladex<sup>®</sup> is commonly given with oral chemotherapy drugs as part of a prostate cancer regimen.

**Pipeline:** Significant new drug development does not appear to be taking place in the area of LHRH analogs. The primary focus will continue to be designing delivery systems that are effective and long-acting, thereby decreasing the number of injections needed over a period of time.

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### ***Tumor Necrosis Factor Inhibitors***

#### **Primary Uses: Rheumatoid Arthritis, Crohn's Disease and Psoriasis**

Part of the body's immune system, tumor necrosis factor (TNF) is a protein that helps stimulate the body's response to infection or disease. It gets its name because one of its first known activities was the breakdown of certain cancer cells. Since its initial discovery, TNF has been implicated as a cause of cachexia, which is the loss of lean body mass in patients with cancer, and as an inflammatory mediator in diseases such as rheumatoid arthritis (RA), Crohn's disease and psoriasis. Joint destruction can also occur when TNF levels are high. Drug therapy is designed to target circulating TNF and block its effects.

Three TNF-inhibitors are currently on the market. They differ in chemical composition, approved uses and methods of administration. The first anti-TNF drug was Remicade®, approved by the FDA in August 1998 for the treatment of Crohn's disease. Since its initial approval, Remicade® has received approval for use in RA. It is given in a physician's office by intravenous infusion every 4 to 8 weeks depending on the severity of the disease. The FDA approved the second TNF-inhibitor, Enbrel®, in November 1998. First approved for use in RA, Enbrel® has since added additional indications for juvenile RA and psoriatic arthritis, which is arthritis caused by the skin disease psoriasis. It is self-administered twice weekly by subcutaneous injection. Remicade® and Enbrel® received additional competition at the end of 2002 when the FDA approved Humira™ for the treatment of RA. Like Enbrel®, Humira™ is a self-administered subcutaneous injection. However, Humira™ is given less frequently than Enbrel®, with an every-other-week dosage regimen.

**Pipeline:** The pipeline for TNF-inhibitors is quite large, in both the number of products and the number of new uses for existing products. Each of the currently marketed TNF-inhibitors is being studied for effectiveness in psoriasis, a disease with few effective treatment options. Remicade® is being studied for asthma to see if the anti-inflammatory effects seen in RA and Crohn's disease can be applied to a respiratory disease. Efforts are also under way to simplify dosage regimens. Once-weekly injections are being studied for Enbrel®. A subcutaneous version of Remicade® that is in development would allow self-injections. On the new drug front, the closest product to market is likely CDP-870, which offers monthly subcutaneous dosing. Other unique drugs in development include oncept, a TNF-binding protein; and DPC 333, an oral therapy to inhibit an enzyme that produces TNF.

### ***Colony Stimulating Factors***

#### **Primary Use: Increasing White Blood Cells in Cancer Patients**

White blood cells called neutrophils are the body's primary defense against infections. A low number of neutrophils in the body is called neutropenia. Neutropenia is a serious condition, because even the smallest infection can cause serious complications or even death. The condition occurs most often in people receiving chemotherapy for cancer and in bone marrow transplant recipients. Cancer chemotherapy drugs are so strong and toxic that they often destroy healthy cells in addition to the cancerous cells. During the time that the body takes to regenerate healthy white cells, patients are at the greatest risk of infection. Many years ago the only course of action was trying to prevent infections by administering multiple antibiotics while waiting for the body to regenerate new white blood cells from the bone marrow. In recent years, new therapies that

directly stimulate the bone marrow into producing more white blood cells were developed. These therapies, called colony stimulating factors, reduce the risk of serious infections, allowing patients to stay on their scheduled cancer chemotherapy regimens.

Three colony stimulating factors are currently on the market. The first two, Neupogen® and Leukine®, were approved in 1991, and the third, Neulasta™, in 2002. Neupogen® and Neulasta™ contain the same active drug but differ in their methods of administration. Neupogen® is given on a daily basis, either subcutaneously or intravenously, until the patient's white blood cell count is at an acceptable level, which can be up to 2 weeks for chemotherapy patients and even longer for bone marrow transplant patients. A long-acting form of Neupogen®, Neulasta™ is given by subcutaneous injection at the start of each chemotherapy cycle. Leukine® is a slightly different form of colony stimulating factor used for specific types of cancer and in bone marrow transplantation. It is given primarily as an intravenous infusion, but it can also be given subcutaneously.

**Pipeline:** Because neutrophils are the body's natural defense against infection and because some current therapies specifically target neutrophils, opportunity for new drug development is limited. It is possible that new therapies could further enhance the delivery of drugs to the body or perhaps complement existing therapies, but no such therapies are in advanced clinical trials.

### **Erythroid Stimulants**

#### **Primary Use: Increasing Red Blood Cells in Patients with Kidney Disease or Cancer**

The body manufactures two different types of blood cells: white blood cells, some of which are described above, and red blood cells (erythrocytes), which have the primary purpose of carrying oxygen from the lungs to the rest of the body. Red blood cells are generated in the bone marrow, and their production is stimulated by a protein called erythropoietin. When the circulating amount of red blood cells is decreased, anemia results. Conditions that can cause anemia include kidney disease and chemotherapy for certain kinds of cancer. If the body's own bone marrow cannot generate enough new red blood cells to replace those lost by disease or drugs, a blood transfusion is usually necessary. Research done in the 1980s led to the development of an erythroid stimulant — recombinant erythropoietin — which is used to supplement the body's own erythropoietin and limit the occurrence of anemia and the resulting need for blood transfusions.

The current recombinant erythropoietin market consists of three products, two of which are the same molecule. The first product, Epogen®, was approved in 1989 for use in patients with advanced kidney disease, including dialysis patients. The company that discovered and developed Epogen® then licensed certain rights of the product to another company, and the drug was brought to market in 1990 as Procrit®, which is used for anemia related to cancer chemotherapy. Even though the two different products, Epogen® and Procrit®, are being marketed for different diseases, the active ingredient, erythropoietin, is the same in both products. In 2001, a next-generation erythropoietin product, Aranesp™, was brought to market for anemia caused by either kidney disease or chemotherapy. Aranesp™ is a slightly modified version of erythropoietin that is approved for less frequent dosing than Epogen® and Procrit®.

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**Pipeline:** Opportunities for new drugs to compete in the class of erythroid stimulants may prove difficult, as existing therapies provide supplemental erythropoietin to the body's own stores of the protein. However, research is being done on compounds that enhance the delivery of erythropoietin to the cells that need it. One such method of enhancing delivery is through gene activation. Currently, supplemental erythropoietin is produced by inserting the gene for human erythropoietin into the cell of an animal, where it is grown for mass production. Gene activation takes place within the human cell by "turning on" the gene to produce more erythropoietin. Another method of erythropoietin delivery, in very early stages of development, uses inactive erythropoietin that is injected, stored in the body and then activated by an oral drug.

### **Growth Hormone**

#### **Primary Use: Growth Hormone Deficiency**

Growth hormone is secreted by the pituitary gland. When it reaches the liver it stimulates the production of another hormone, called insulin-like growth factor one (IGF-1), which is responsible for the effects typically associated with growth hormone. Growth hormone deficiency occurs when the production of growth hormone is disrupted. Initially, growth hormone was obtained from human cadavers. That practice was stopped in the 1980s, when therapy was shifted to recombinant versions of human growth hormone. Therapy with growth hormone can be divided into three categories: patients with documented growth hormone deficiency, patients with short stature due to a concomitant disease and patients with muscle wasting due to AIDS.

The first recombinant growth hormone, Protropin<sup>®</sup>, was approved in 1985 for use in children with growth failure. Protropin<sup>®</sup> was soon followed by several products (Humatrope<sup>®</sup>, Nutropin<sup>®</sup>, Genotropin<sup>®</sup>, Norditropin<sup>®</sup> and Saizen<sup>®</sup>). All of these products are approved for use in children with growth hormone deficiency and some are also approved for use in adults. An additional growth hormone product, Serostim<sup>®</sup>, was approved by the FDA in 1996 for the treatment of AIDS wasting, a disorder in which the body uses lean muscle mass instead of stored body fat for energy. All growth hormone products can be self-administered as subcutaneous injections, and most are given on a daily or almost-daily basis. Nutropin<sup>®</sup> is also available as a long-acting depot formulation, which reduces the number of injections to one or two per month.

**Pipeline:** The development of new drugs to treat growth hormone deficiency focuses on alternative delivery systems. At least two oral versions of growth hormone are being developed, as is a nasal version, although each is a number of years from the market. A fourth product contains growth hormone attached to the protein albumin. This design may allow for less frequent dosing.

### ***Intravenous Immune Globulin (IVIG)***

#### **Primary Use: Immunodeficiency Caused by Genetics, Cancer or HIV**

IVIG products are used for immunodeficiencies, conditions in which the body's immune system is not working properly. The immune system is the body's defense against infection, and it consists of many different types of cells and proteins. When these cells and proteins fail to work properly, the body is more susceptible to infections. The most common immunodeficiency is caused by a genetic defect that is usually passed from parents to children. Immunodeficiencies present at birth are called primary immunodeficiencies. More than 70 different forms of primary immunodeficiencies, with varying levels of severity and incidence, have been identified to date.

IVIG is a therapy for patients with immunodeficiencies caused by a lack of antibodies. Antibodies are large proteins, also known as immunoglobulins, which attach to foreign substances, such as bacteria, and "hold" them until another immune cell, the macrophage, destroys them. Without enough circulating antibodies, persons with an immunodeficiency are more susceptible to even the mildest infections. Something as simple as a cold can be very serious to a person with an immunodeficiency. IVIG is given to these patients to provide a higher level of circulating antibodies that work to prevent future infections. IVIG is made from human blood that has been purified to prevent contamination. Typically, it is administered by intravenous infusion, either at home or at a medical clinic. Therapy with IVIG is repeated every 3 to 4 weeks for the patient's lifetime. IVIG products include Gammagard<sup>®</sup>, Venoglobulin<sup>®</sup>-S, WinRho SDF<sup>®</sup> and Gamimune<sup>®</sup> N. Each of these products is a unique formulation; not all have the same FDA-approved uses.

**Pipeline:** Current research in the area of immunodeficiencies focuses on both drug and non-drug therapies. Gene therapy is the most active area of research. Because a primary immunodeficiency is the result of a genetic defect, research is being done to see if inserting healthy genes into the cells of an immunodeficient patient results in the production of healthy cells. Early results are encouraging, but widespread treatment with gene therapy is years away. Other genetic research is being conducted using stem cells, which are cells taken from umbilical cord blood. When pregnancy screening indicates that a primary immunodeficiency is probable, umbilical cord blood is collected during delivery, the stem cells are taken out and modified genetically, then they are transfused into the child. This technique is also years away from widespread use.

### ***Clotting Factors***

#### **Primary Use: Hemophilia**

Typically seen in males, hemophilia is an inherited bleeding disorder caused by a shortage of blood-clotting factors. A person with hemophilia has an excessive risk of bleeding. The two different types of hemophilia are called A and B. Hemophilia A, also called classic hemophilia, is the most common, and it is caused by a deficiency in clotting factor VIII. Hemophilia B is caused by a deficiency in clotting factor IX. An additional bleeding disorder, von Willebrand's disease, is related to the function of platelets, cells that assist with blood clotting.

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The treatment of hemophilia requires administration of clotting factors. Historically this was accomplished by blood transfusions, but the amount of clotting factors in a typical transfusion was not enough to treat the bleeding disorder sufficiently. In the 1960s, a concentrated form of factor VIII, also known as cryoprecipitate, was discovered. Administration of cryoprecipitate did not require a blood transfusion, which was beneficial to patients. A few years later, the introduction of freeze-dried forms of factor VIII and factor IX, derived from human blood plasma, allowed hemophilia patients to administer clotting factors at home. Unfortunately, some of these earlier products were contaminated with viruses, so even though hemophilia patients were able to control their bleeding disorder, a few patients were infected with diseases such as HIV or hepatitis. More recent products are recombinant in nature or are highly purified, so the risk of infection essentially has been eliminated. Recombinant factor VIII products include Kogenate® FS, Recombinate™ and Refacto®, while plasma-derived products include Alphanate®, Humate-P®, Hemofil® M, Monarc-M™ and Monoclote-P®. For factor IX, the only recombinant product is BeneFix®, and common plasma-derived products include AlphaNine® SD and Monenine®. The dosing of clotting factors is highly variable since it is based on patient weight as well as on the severity of disease. All clotting factors are given intravenously, and most patients self-infuse at home.

**Pipeline:** As with several other diseases, the most intriguing research in the field of hemophilia is gene therapy. The gene that causes hemophilia is known, and if this gene were to be modified to become a "normal" gene, hemophilia might be cured. Several gene-therapy products are in clinical trials, including both factor VIII and factor IX products. It will likely be a number of years before these products make it to market. Closer to market are recombinant products that are free of any forms of albumin, which has been linked to impurities (and resulting infections) in the past.

*Actions*

DRUG FIELD ID

2002

REDACTED

## Actions to Mitigate Impact of Cost Trend

The annual growth in PMPY ingredient costs continued to rise in 2002, reaching an all-time high of 18.5 percent. Inflation and utilization rate increases were substantial, 7.5 percent and 6.3 percent, respectively. Over the next 5 years, Express Scripts anticipates that PMPY prescription drug costs will continue to increase at still substantial but somewhat lower annual rates of growth as more generic products are prescribed when brand products lose patent protection.

Employers, health plans and other plan sponsors confront numerous challenges as they strive to continue providing an affordable drug benefit to their employees and members in this environment of rising pharmacy costs. The various approaches plan sponsors can adopt in dealing with the challenges of rising drug costs are presented in the remainder of this section.

### *Take Advantage of Generics*

As noted in the introduction, a number of significant brands recently have lost or soon will lose patent protection. In turn, the cost-saving potential for the plan sponsor and member can be substantial. However, generic availability does not automatically translate into cost savings. Delays in patent expiration, the introduction of new strengths and dosage forms, the lack of generic product marketing relative to brands, and the development of new brand products can limit the cost-saving potential of generics.

As illustrated in last year's *Drug Trend Report*, the typical life cycle of a prescription chemical entity may mitigate the potential that generic product availability can have as a cost-management strategy. Market share begins to decline prior to generic availability. The market share erosion of these brand-name, soon-to-be generic products varies, depending on whether strong competition exists within the class and/or whether a new, innovative brand product is waiting to capture market share. Even after the generic becomes available, the market share of that chemical entity (now the brand and generic versions combined) continues to decline for two reasons. First, generic drug manufacturers are essentially in competition with themselves. One manufacturer may make the same product for several other companies to distribute, or several manufacturers could be producing and distributing the same generic product. Consequently, it is not in the interest of generic manufacturers to spend money to advertise their specific generic product, because the benefit will be shared by competing generics. Second, the economics of the generic industry leave it with far fewer dollars for product promotion than brand-name competitors. Market share typically levels off at a point significantly below the brand drug's peak market share level.

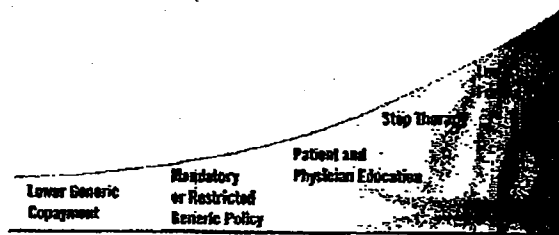
To optimize the cost-savings potential of generics, plan sponsors should counteract such tactics by effectively promoting the appropriate use of generics. Programs that promote generics can be depicted on a continuum of intensity as is shown in Figure 11. Each of these programs is reviewed on the following pages.

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Figure 11  
Continuum of Approaches to Maximizing Generic Opportunities



**Lower Generic Copayment:** One of the most important strategies for promoting generic use is to keep the generic copayment low — \$5 to \$7.50. Lower copayments provide members with a financial incentive to use generics rather than brands. In addition, based on Express Scripts' research, the brand copayment should be at least \$8 to \$10 higher than the generic copayment for members to have adequate incentive to use generics when appropriate. Plan sponsors that have increased generic copayments to \$10 or more in recent years may want to consider decreasing the generic copayment and, correspondingly, increasing the brand copayment. Although consumers are somewhat insensitive to prescription copayment changes, offering them a substantially lower generic copayment will lead to increased generic use. Also, at a \$10 copayment for generics, plan sponsors will be asking members to pay more than 50 percent of the cost of many generics.

**Mandatory or Restrictive Generic Policy:** A generic policy represents a sound way to optimize the use of generics. Under a mandatory generic program, the member pays the generic copayment plus the cost differential between the multi-source brand and its generic equivalent, regardless of whether the physician allows generic substitution. In a restrictive generic program, the member pays the generic copayment plus the difference between the cost of the multi-source brand and its generic only if the member insists on having the multi-source brand, despite the physician allowing generic substitution. Express Scripts' research indicates that a generic policy provides additional savings even if a plan already has a lower copayment for generics than for brands (i.e., a two-tier or three-tier copayment). As reported in the 2001 *Drug Trend Report*, about two-thirds of the consumers who were surveyed said that generics are as good as brands, suggesting that generics are acceptable to a substantial majority of consumers. More importantly, the minority of consumers who disagreed thereby indicated their willingness to pay more for the brand medication. Accordingly, a generic policy represents a sound benefit design approach. Indeed, three-fourths of Express Scripts clients have either a mandatory or restrictive generic policy.

**Patient and Physician Education:** Efforts to encourage greater use of generics may be limited by physicians' unwillingness to prescribe them, as well as by consumers' reluctance to use them. While consumers are generally supportive of generics, a key challenge is that members often are not aware that a generic alternative is available, particularly when the generic is a different chemical entity — a therapeutic alternative — from the medication prescribed. This lack of awareness may seem surprising given the continued growth in consumerism. However, brand-name advertising messages, coupled with a lack of generic awareness among physicians, both contribute to a lack of generic awareness among consumers.

On the flip side, 85 percent of respondents to a February 2002 national survey conducted by Knowledge Networks for Express Scripts said they wanted information on ways to save money on prescription drugs. This percentage grows to 91 percent for respondents aged 55 to 64. When these higher utilization groups understand and respond to savings opportunities, the positive financial effect is even greater.

When addressing topics such as personal health and prescription drugs, messages from well-known sources have the greatest effectiveness. To get the most value from member education, PBMs and plan sponsors should collaborate so that members recognize the source of the information. Survey participants indicated that co-branded materials sent from familiar sources are more likely to gain their attention.

Patient education about generic medications can take many forms. Express Scripts offers an Internet tool that lets members view their out-of-pocket cost for a drug, as well as the cost of an available generic alternative when a brand-name drug is requested. This PriceCheck™ feature lets members see what they will pay for their prescriptions before having them filled at the pharmacy. It gives members the information needed to make cost-effective choices about their medication alternatives — choices that provide savings for both the member and the plan sponsor. Express Scripts' research shows the power of providing the right kind of information at the time the consumer is making a decision. Approximately 59 percent of members who had a mail benefit and who used PriceCheck™ to price maintenance medications began using mail service for these prescriptions.

For plan sponsors with a concentration of members in a given geographic region, physician outreach should be considered as part of a patient and physician education strategy to promote generics. Research has shown that physicians are not always receptive to prescribing generics. However, academic detailing with physicians can be effective at altering fundamental prescribing patterns. These programs are successful because they provide physician-specific prescribing profiles, use a clinician to discuss the merits of generics and provide rigorous clinical evidence that supports the appropriateness of the generic.

Beyond academic detailing, the next evolution in promoting optimal physician prescribing is RxHub, an independent venture formed by Express Scripts, AdvancePCS and Medco Health Solutions to advance the efficiency and safety of the prescription writing process. RxHub will address the information gap that exists among physicians, pharmacies, health plans and PBMs. The system created by RxHub allows physicians who use electronic prescribing devices

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to connect directly to PBMs, access patient-specific coverage information (including the appropriate formulary) and receive real-time notification of potential drug interactions and side effects. The resulting prescription can be sent electronically to the patient's preferred pharmacy for fulfillment. Through RxHub technology, prescription use can become more cost-effective and safer.

**Step Therapy:** A step therapy program requires the member to try a less expensive drug, such as a generic, for a specified period of time before the plan sponsor will pay for the originally prescribed medication. The unprecedented availability of generics provides a wealth of clinically and financially appropriate step therapy opportunities. In addition to the immediate savings achieved, step therapy represents a longer-term strategy for encouraging generic use, because physicians' prescribing habits may change.

**Low-Cost Formulary:** The most aggressive strategy a plan sponsor can adopt to promote the use of generics is to implement a low-cost formulary — a closed formulary consisting primarily of generic products. As more branded products lose patents, it is possible to increase the use of generics through formulary design. The only branded products covered in the low-cost formulary are in therapy classes without a clinically equivalent generic. A low-cost formulary focused on generics will provide substantial savings to a plan sponsor because it represents the most effective strategy to promote generics.

#### ***Designing the Prescription Benefit Plan***

Although the promotion of generics is a critical cost-management approach, an overall cost-management strategy must be more comprehensive. Four key steps are involved in designing an overall cost-management strategy.

##### **Step 1: Formulary Development**

Formularies, which are lists of covered or preferred drugs, are the backbone of pharmacy benefit design. Through an independent Pharmacy and Therapeutics Committee, Express Scripts offers a range of formularies to meet the varying needs of plan sponsors. In formulary development, a drug's clinical benefit, AWP, potential member and physician disruption and upcoming market dynamics (e.g., new generics) are all considered.

##### **Step 2: Cost-Sharing Structure**

After establishing a formulary, one of the first questions a plan sponsor addresses is whether to institute copayments or coinsurance. Express Scripts' research shows similar drug use patterns among co-insurance and copayment plans. The only evident advantage of co-insurance is that cost-sharing automatically keeps up with drug cost increases, while copayment designs require copayment increases every few years. However, because of the unpredictability of out-of-pocket costs for members, about 13 percent of Express Scripts members with an integrated benefit have co-insurance. When selecting a copayment structure, a plan sponsor can institute one, two, three or more levels. Nearly 55 percent of members with an integrated retail and mail benefit are enrolled in a three-tier copayment plan in which the lowest copayment is for generics and the highest for non-formulary brands, with the middle tier reserved for formulary brands.

Three-tier copayments respond to growing consumerism by allowing members to save money through choosing the less expensive therapeutic alternative. In a study published in *Medical Care*,<sup>33</sup> Express Scripts found that the three-tier structure resulted in significant savings for plan sponsors while having no effect on emergency room use, inpatient hospital visits or physician office visits. Some plan sponsors, seeking even more trend management, are instituting a closed formulary that only covers generic and formulary brand medications. An Express Scripts' study found a substantial savings in drug expenditures for a plan that implemented a closed formulary relative to a matched comparison sample with an open formulary.<sup>34</sup>

#### Step 3: Copayment Amount

Regardless of whether a plan sponsor opts for a two- or three-tier copayment plan, it is important that the level of copayments be set appropriately. To align plan sponsor and member incentives, Express Scripts recommends cost-sharing targets by tier of about 20 percent for generics, 20 percent for formulary brand-name drugs and 40 percent for non-formulary brand-name drugs. In 2002, the typical three-tier plan for Express Scripts clients was under \$10 for generics, almost \$20 for formulary brand drugs and over \$35 for non-formulary brand drugs.

#### Step 4: Point-of-Service (POS) Programs That Reinforce Benefit

Formulary and cost-sharing choices can be reinforced real-time through the POS system. Plan sponsors can easily implement benefit exclusions, quantity limits, step therapy, and mandatory and restrictive generic programs at the time the claim is submitted for adjudication. Prior authorization (PA) programs require a patient to meet certain age requirements or have a documented diagnosis to receive a prescription of a given medication. A recent unpublished Express Scripts' study found that PA provides significant plan sponsor savings.

Before deciding to implement plan design changes, many plan sponsors factor into their decision-making process the potential impact such changes could have on member satisfaction. For example, whenever a plan sponsor changes the copayment amount, the potential member impact is an important consideration. An unpublished Express Scripts' study found that copayment changes produced a temporary increase in call center volume, which returned relatively quickly to call levels prior to the change. For every additional call related to a plan design change, the plan sponsors studied saved between \$116 and \$698.

Injecting an element of member choice can be central to mitigating the negative effect of plan changes on member satisfaction. Member choice is an underlying characteristic in tiered copayment systems. In a two-tier copayment system, the member has the choice between paying a less expensive generic copayment or a higher brand copayment, assuming that the drugs are therapeutically equivalent. In a three-tier copayment system, the member potentially has even more choice — an inexpensive generic copayment, a higher formulary brand copayment and an even higher non-formulary brand copayment.

33. Mothral BR, Feinman KA. Effect of a three-tier prescription copay on pharmaceutical and other drug utilization. *Medical Care*. 2001;39(12):1293-1294.

34. Mothral BR, Henderson RR. The effect of closed formularies on prescription drug use and costs. *Inquiry*. 1999;20(3):481-491.

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Express Scripts also helps plan sponsors enhance member satisfaction through a pharmacy benefit strategy called Express Choice™, which enables sponsors to offer multiple pharmacy plans from which members can choose. This approach responds to consumer choice and at the same time ties pharmacy use more directly to member financial responsibility. For example, an employer could provide one package for all drugs, regardless of the type of condition the drug treats, and another package that excludes coverage of drugs that have less expensive alternatives and of drugs used for cosmetic purposes. The employee selecting the richer benefit pays the incremental costs attached to the coverage of additional drugs. In addition to drug coverage, plan options can vary in the size of the retail pharmacy network and in the number and magnitude of copayments, as well as in other features such as the inclusion of a mandatory generic program. A member choice plan provides the employee open access to all drugs, but places part of the financial burden on the employee for his or her choices. One important consideration when adopting this strategy is whether to maintain some element of insurance in the pricing decision. A key assumption in insurance is that the price of the benefit should be spread across both the healthy and sick or, put another way, between low- and high-utilizers. This principle entails low-utilizers subsidizing the costs of high-utilizers. Calibrating the expected distribution of high- and low-utilizers across the various options for underwriting purposes is very difficult.

The specter of rising prescription drug costs will remain with us for the foreseeable future. As is evident from the discussion in this Report, there are a number of approaches that plan sponsors can take to manage these drug cost increases. Express Scripts works closely with clients to develop the specific approaches that best meet the needs of each client.

*Appendix A*

DRUG TREND

2002 Report

## Drug Therapy Class Review

In 2002 the top 25 therapy classes accounted for 81.2 percent of total PMPY ingredient costs. The utilization of the major medicines within each of the 25 classes between 1998 and 2002 is presented, along with their 2002 PMPY ingredient cost. All drugs, both those classified in this Report as common and new, are included in this analysis. The discussion in this Appendix focuses primarily on changes that occurred between 2001 and 2002. Drugs that are in the pipeline and that have the potential to significantly affect a specific class in the next several years are also presented.

Table A1  
Cost Per Prescription and PMPY Cost for Major Therapy Classes 2001-2002

Therapy Class	2001 COST/Rx	2002 COST/Rx	% CHANGE	2001 \$ PMPY	2002 \$ PMPY	% CHANGE
Gastrointestinals	\$97.99	\$106.55	8.7%	\$42.75	\$53.60	25.4%
Antihypertensives	\$72.79	\$79.44	9.1%	\$41.83	\$51.77	23.8%
Anticoagulants	\$68.18	\$69.56	2.0%	\$42.51	\$50.46	18.7%
Antihyperlipidemics	\$34.09	\$36.09	5.9%	\$26.41	\$30.57	17.3%
Anti-Rheum (NSAIDs)	\$66.60	\$71.03	6.7%	\$25.72	\$28.66	11.4%
Antidiabetics	\$55.53	\$58.30	5.0%	\$22.39	\$25.66	14.6%
Antiestrogens	\$50.58	\$62.56	19.7%	\$18.13	\$22.27	22.8%
Antihistamines	\$54.09	\$58.93	9.0%	\$17.89	\$21.89	21.2%
Antivirals	\$182.27	\$243.29	33.5%	\$25.85	\$15.59	43.6%
Dermatologicals	\$46.37	\$49.64	7.1%	\$14.37	\$15.95	4.8%
Narcotic Analgesics	\$29.03	\$32.29	11.2%	\$12.30	\$14.59	21.9%
Misc. Endocrines	\$50.03	\$93.40	3.7%	\$11.80	\$14.82	25.6%
Anticoagulants	\$70.98	\$82.73	16.6%	\$12.66	\$14.26	12.6%
Anticancer	\$220.66	\$258.25	17.0%	\$11.27	\$14.63	29.4%
Calcium Blockers	\$42.41	\$43.56	2.7%	\$13.57	\$13.73	1.2%
Estrogens	\$23.40	\$23.12	7.3%	\$11.62	\$11.04	-5.0%
Oral Contraceptives	\$25.97	\$26.42	1.7%	\$8.90	\$10.65	19.6%
Beta Blockers	\$22.47	\$24.59	9.4%	\$8.80	\$10.53	19.6%
Cough/Cold	\$27.37	\$30.74	12.3%	\$8.52	\$9.69	13.6%
Decongestants	\$48.01	\$54.34	13.2%	\$7.15	\$8.40	17.4%
Migraine Products	\$126.91	\$132.66	4.5%	\$7.03	\$8.25	17.4%
Quinestones	\$72.50	\$77.64	7.1%	\$7.67	\$7.70	0.4%
Macrolides	\$38.79	\$41.33	6.5%	\$7.16	\$7.48	4.5%
Penicillins	\$24.45	\$24.82	1.5%	\$7.21	\$7.36	2.0%
Antipsychotics	\$101.99	\$115.92	14.6%	\$5.47	\$6.94	26.9%
Top 25	\$52.04	\$57.38	10.3%	\$401.41	\$475.60	18.5%
Other	\$32.15	\$36.07	12.2%	\$92.79	\$119.00	28.5%

### Market Share Table Legend

PERCENTAGE CHANGE IN PMPY COST FROM 2001-2002

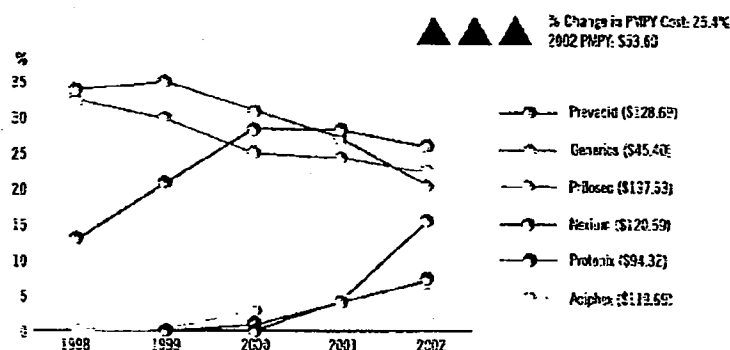
▲▲▲▲▲ 30+ ▲▲▲▲ 20-29 ▲▲▲ 10-19 ▲ 0-9 ▼ LESS THAN 0

2002 average costs (representing average prescription cost) are reported following each drug name in the legend for each Market Share Trend Figure.

## GASTROINTESTINALS

According to the American College of Gastroenterologists, over 15 million Americans may have acid indigestion every day, and up to 60 million have it at least once a week. About 20 million U.S. citizens will have a peptic ulcer sometime in their lives.<sup>1</sup> With an estimated prevalence of about one case per 1,000 members of the population, chronic inflammatory bowel diseases (IBDs) such as Crohn's disease and ulcerative colitis will affect as many as a million Americans.<sup>2</sup> Another disorder of bowel function, irritable bowel syndrome (IBS) affects about 10 percent to 20 percent of American adults — more commonly women than men.<sup>3</sup> Not an inflammatory condition, IBS is characterized by changes in bowel habits.

Figure A2  
Therapy Class Drug Market Share Trend — Gastrointestinals



- PMPY ingredient costs for gastrointestinals grew by over 25 percent to \$53.60 in 2002. Most of this increase was due to higher utilization rates, primarily coming from higher prevalence rates.
- A generic for Prilosec<sup>®</sup> (omeprazole) received final FDA approval, but its introduction was delayed while patent litigation was resolved. When the generic was finally marketed in December 2002, only one manufacturer had the authority to produce it. As a result, supplies are limited, and the price is relatively high. The expected launch of a non-prescription version, tentatively named Prilosec-1<sup>®</sup>, is also on hold after the FDA asked the manufacturer to conduct additional labeling comprehension studies.

1. American College of Gastroenterologists, Common GI Problems: Volume 1. No Date Given. Available at: <http://www.acg.org/acg-journal/patientinfo/cgicgpcv1.html>. Accessed October 17, 2002.

2. Friedman S. Inflammatory bowel disease: Crohn's disease. Last reviewed August 5, 2002. Available at: [http://www.veritasmedicine.com/id\\_home.cfm?id=10&bit=hl&type=DC&page=1](http://www.veritasmedicine.com/id_home.cfm?id=10&bit=hl&type=DC&page=1). Accessed October 17, 2002.

3. International Foundation for Functional Gastrointestinal Disorders, Inc. About irritable bowel syndrome (IBS). Last updated August 14, 2002. Available at: <http://www.aboutibs.org>. Accessed October 17, 2002.



- Despite costing more than twice as much as generic H2 blockers (ranitidine and cimetidine), the market share of PPIs continued to grow, reaching almost three-fourths of the class in 2002. Prevacid<sup>®</sup>, Prilosec<sup>®</sup> and its successor product, Nexium<sup>®</sup>, dominated the PPI market.
- Nizatidine, the generic for Axid<sup>®</sup> capsules, was launched in September. Both prescription and OTC strengths continue to be marketed.
- In late 2002, the proton pump inhibitor, Aciphex<sup>®</sup> (rabeprazole), received a new indication for *H. pylori* eradication in combination with amoxicillin and clarithromycin. The regimen is to be used for 7 days.
- Remicade<sup>®</sup> (infliximab) was FDA-approved in June 2002 for an expanded indication in the treatment of Crohn's disease. It is a monoclonal antibody that binds permanently to a mediator of inflammation called tumor necrosis factor-alpha (TNF-alpha). Remicade<sup>®</sup> was previously approved for the treatment of Crohn's disease and rheumatoid arthritis (RA).
- Zelnorm<sup>®</sup> (tegaserod), a serotonin-4 receptor agonist, was approved by the FDA in July for the short-term treatment of women who have IBS with constipation as the primary symptom. The approval of Zelnorm<sup>®</sup> followed the very unusual re-introduction of Lotronex<sup>®</sup> (alosetron), which was removed from the U.S. market in late 2000 after reports of serious side effects. Lotronex<sup>®</sup> is being dispensed again on a limited basis for women whose chief symptom of IBS is diarrhea.
- IBStat<sup>®</sup> (hyoscaryamine oral spray) is a new dosage form of a drug used as add-on therapy to help control cramps and pain associated with IBS, and spasms of the colon in adults. It was marketed in the United States in June 2002.
- Photofrin<sup>®</sup> (porfimer), a photodynamic treatment already approved for some cancers, was granted orphan status in June for therapy of Barrett's esophagus. A similar photodynamic therapy, Levulan<sup>®</sup> PDT (aminolevulinic acid) is in Phase II trials to eliminate high-grade dysplasia in Barrett's esophagus.
- Humicade<sup>™</sup> (CDP 571) is a monoclonal antibody that finished two Phase III trials for Crohn's disease in 2002. While it did not meet the clinical goals set for the studies, it did provide some improvement when administered intravenously once every 8 weeks. Further studies are planned.
- Phase III studies for CDP 870, another monoclonal antibody that binds to TNF-alpha, began in early 2003. Currently being tested for both Crohn's disease and RA, CDP 870 will require only a monthly subcutaneous injection.

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- Antegren® (natalizumab), the first in a new class of drugs called selective adhesion molecule (SAM) inhibitors, is also in Phase III trials for Crohn's disease. Antegren® is believed to block a specific adhesion molecule known as alpha-4 integrin, thereby keeping immune T-cells away from areas of inflammation.
- ISIS 2302 (alicaforfen) is in Phase III trials as an intravenous formulation and in Phase II trials as an enema for people with Crohn's disease. Alicaforfen is an antisense drug that inhibits I-CAM 1, a cellular adhesion molecule present in a number of inflammatory conditions.
- Phase III trials have been initiated in Europe and the United States for citanetron, a 5-HT3 antagonist for the treatment of diarrhea-predominant IBS. Also in Phase III testing for IBS is dexloxiplumide, which appears to be effective for those with constipation as the major symptom. Dexloxiplumide works by increasing motility of the bowel.
- Results of Phase II studies for RDP58, a "rationally-designed peptide" that inhibits natural chemicals involved in activating inflammation and immune responses, are expected in 2003. RDP58 is in testing for IBD, as well as for other autoimmune diseases and for chemotherapy-induced diarrhea.

## CENTRAL NERVOUS SYSTEM

In any one-year period, approximately 22 percent of American adults suffer from some form of diagnosable mental disorder as defined by the *Diagnostic and Statistical Manual of Mental Disorders-fourth edition, text revised* (DSM-IV-TR).<sup>4</sup> DSM-IV-TR is the American Psychiatric Association's guide to diagnosing and treating mental disorders.

In addition to depressive and anxiety disorders, mental disorders include:

### Attention-Deficit/Hyperactivity Disorder (ADHD)

According to the Centers for Disease Control and Prevention, 3 percent to 7 percent of American children between the ages of 6 and 11 have been diagnosed with ADHD.<sup>5</sup> About three times as many boys as girls are diagnosed with ADHD. Once thought to be a condition affecting only children, ADHD is now believed to persist into adulthood for up to two-thirds of the children diagnosed with it.<sup>6</sup>

- A once-daily formulation of methylphenidate was approved during 2002 under the brand name Ritalin® LA.
- A supplemental new drug application (NDA) was filed in December 2002 for Adderall XR® (mixed salts of a single-entity amphetamine product) in the treatment of adult ADHD.
- Strattera® (atomoxetine) was approved in November for treating children, adolescents and adults with ADHD. A non-stimulant, non-controlled drug, Strattera® is taken once or twice daily.
- In August 2002, the FDA accepted for review an NDA for MethyPatch®, a once-daily transdermal methylphenidate patch. In clinical trial results, the patch was significantly better than placebo in controlling behavior as measured by rating scales and by direct observation.

### Eating Disorders

Estimates are that between one percent and 4 percent of adolescent and young adult women and about one percent of men in the same age groups suffer from an eating disorder, most commonly anorexia nervosa, binge eating or bulimia.<sup>7</sup>

4 National Institute of Mental Health. The numbers count. Mental disorders in America. Updated January 1, 2001. Available at: <http://www.nimh.nih.gov/publicat/numbers.cfm>. Accessed January 6, 2003.

5 National Center on Birth Defects and Developmental Disabilities. Centers for Disease Control and Prevention. What is attention-deficit/hyperactivity disorder (ADHD)? Last updated November 9, 2002. Available at: <http://www.cdc.gov/nbdds/edhd/what.htm>. Accessed January 13, 2003.

6 Children and Adults with Attention-Deficit/Hyperactivity Disorder (CHADD). ADHD in adults - fact sheet #7. No Date Given. Available at: <http://www.chadd.org/ts/ts7.htm>. Accessed January 13, 2003.

7 Anorexia Nervosa and Related Eating Disorders, Inc. Statistics: how many people have eating disorders? Updated June 2002. Available at: <http://www.anred.com/stats.html>. Accessed January 13, 2003.



- Studies of Nectrofin® (ketepirrim) for AD have been suspended after treatment with the drug failed to show significant difference from treatment with placebo in trials of AD patients.
- Phase II studies have begun in the United States for a novel type of AD drug, Abzhemed™ is a small organic molecule that appears to prevent the formation of the amyloid plaques characteristic of AD.
- Research into drugs used in treating other conditions continues for AD patients. Further data presented at the International Conference on Alzheimer's Disease and Related Disorders seems to reinforce previous reports that cholesterol-lowering medications might be used to treat and even prevent AD. Antipsychotic medications, Serequel® (quetiapine), Zyprexa® (olanzapine) and Risperdal® (risperidone) are being studied for the treatment of Alzheimer's-related psychoses.

#### Multiple Sclerosis (MS)

MS, the most frequently diagnosed neurological disease among young adults, affects 350,000 to 500,000 U.S. citizens. It occurs in more women than men, and it is more common among Caucasians than other ethnic groups. After diagnosis, a person with MS can expect to live 50 years or more.<sup>12</sup>

- In early 2003, Avonex® (interferon beta-1a), which had been approved for relapsing MS, received an additional indication for treating MS patients early in the course of the condition.
- A Phase III trial, BEYOND (Betaseron Efficacy Yielding Outcomes of a New Dose), is under way to test the effectiveness and safety of a high-dose regimen of the already-approved MS treatment, Betaseron® (interferon beta-1b).
- Results from Phase II trials of Antegren® (natalizumab) were released in January 2003. The first member of a new class called selective adhesion molecule (SAM) inhibitors, Antegren® is currently in Phase III trials for MS as monotherapy as well as in combination with interferon beta-1a.

<sup>12</sup> Multiple Sclerosis Foundation. FAQs. What is multiple sclerosis? Reviewed January 2002. Available at: <http://www.msfocus.org/faqs.htm>. Accessed October 4, 2002.

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### Parkinson's Disease (PD)

PD affects between a million and a million-and-a-half Americans<sup>13</sup>, including approximately one percent of people over 60 years old. As shown by some highly-publicized cases in the last few years, however, about 15 percent of PD cases are diagnosed before the victim is 50 years old.<sup>14</sup>

- A fast-dissolving formulation of the PD drug, selegiline, was found "approvable" by the FDA in February. The drug will be launched under the brand name Zelapar<sup>®</sup> (selegiline orally disintegrating tablets) when final approval is given.
- An NDA for the first triple therapy agent for PD was filed with the FDA in August. The product contains fixed doses of levodopa, carbidopa and COMtan<sup>®</sup> (entacapone).
- Pergolide, a generic for the brand name drug Permax<sup>®</sup>, was approved in December. In the same month, a report from the Mayo Clinic associated rare cases of heart valve damage to treatment with Permax<sup>®</sup>.
- Phase III trials that began in 2001 are continuing for a new PD drug, Rotigotine CDS<sup>™</sup> (SPM-962), which is being developed as a transdermal patch.
- A Phase II / III study that began in mid-2002 to test CEP-1347 for treating PD is scheduled to last at least 2 years. The drug inhibits an enzyme believed to activate the destruction of neurons — particularly neurons that produce dopamine.

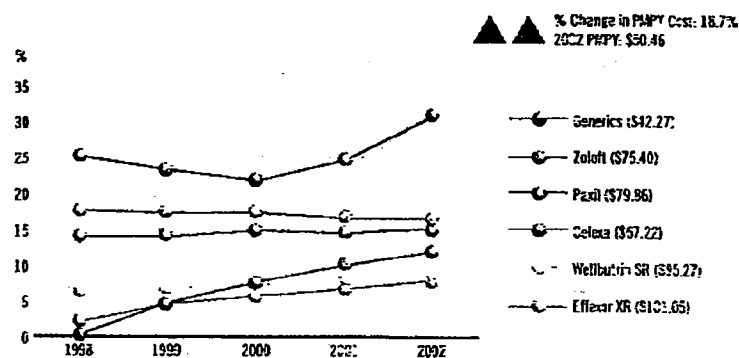
13 Parkinson's Disease Foundation, Inc. Parkinson's disease: an overview. No Date Given. Available at: <http://www.pdf.org/about/disease/overview/index.html>. Accessed October 4, 2002.

14 The National Parkinson Foundation, Inc. What the patient should know. No Date Given. Available at: <http://www.parkinson.org/pdscu.htm>. Accessed October 4, 2002.

### Antidepressants

Around 9.5 percent of adults in the United States experience some type of depression during a typical year. Roughly two-thirds of those 18.8 million people are women.<sup>15</sup>

Figure A2  
Therapy Class Drug Market Share Trend — Antidepressants



- Antidepressants slipped from the second in 2001 to third in 2002 as the most costly therapy class. With a PMPY cost of \$50.46, costs for antidepressants rose almost 19 percent, driven overwhelmingly by increased utilization, principally from higher prevalence rates. The 12.4 percent market share of the less expensive generic Prozac® (fluoxetine) somewhat mitigated the 7 percent inflation rate in the overall class.
- SSRIs continued to make-up the lion's share of antidepressant use. Market shares of Celexa®, Wellbutrin® SR and Effexor® XR rose slightly while the use of other products in the class remained stable or declined somewhat.
- While lawsuits over the patents covering Paxil® (paroxetine) continue, a controlled-release form — Paxil® CR (paroxetine, controlled-release) — was marketed in the spring of 2002 for major depression and panic disorder.
- In May 2002, Zoloft® (sertraline) was granted a new indication for the treatment of premenstrual dysphoric disorder (PMDD). In February 2003, Zoloft® received another new indication for treating social anxiety disorders.

15 National Institute of Mental Health. The numbers count: Mental disorders in America. Updated January 1, 2001. Available at: <http://www.nimh.nih.gov/publico/numbers.cfm>. Accessed January 6, 2002.

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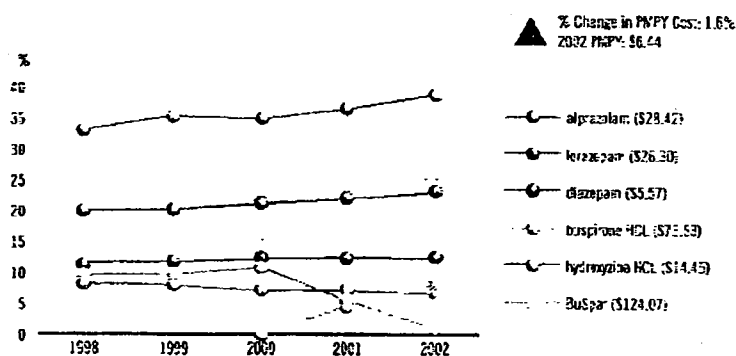
- Lexapro® (escitalopram) received FDA approval in August 2002 as acute and maintenance treatment for major depression. A liquid solution form was given approval later in the year.
- Prozac® (fluoxetine) gained FDA approval in January 2003 for depression and obsessive-compulsive disorder (OCD) in children who are 8 years old or older. In the meantime, a generic for Prozac® oral solution has been launched.
- Also in January, a generic version of the antidepressant Remeron® (mirtazapine) was approved.
- An approvable letter was issued by the FDA in September 2002 for Cymbalta® (duloxetine) in treating depression. Full approval is pending the resolution of labeling and manufacturing details.
- Patent protection for Serzone® (nefazodone) is scheduled to expire in August 2003.

#### Antianxiety Agents

Many people have several types of anxiety disorders at the same time. The National Institute of Mental Health considers the 19.1 million Americans between the ages of 18 and 54 who have anxiety disorders to include:

- 6.3 million with phobias to specific objects or situations
- 5.3 million with social phobia
- 5.2 million with post-traumatic stress disorder (PTSD)
- 4 million with generalized anxiety disorder (GAD)
- 3.3 million with obsessive-compulsive disorder (OCD)
- 3.2 million with agoraphobia
- 2.4 million with panic disorders<sup>16</sup>

Figure A3  
Therapy Class Drug Market Share Trend — Antianxiety Agents



<sup>16</sup> National Institute of Mental Health. The numbers count. Mental disorders in America. Updated January 1, 2001. Available at: <http://www.nimh.nih.gov/publicat/numbers.cfm>. Accessed January 6, 2003.

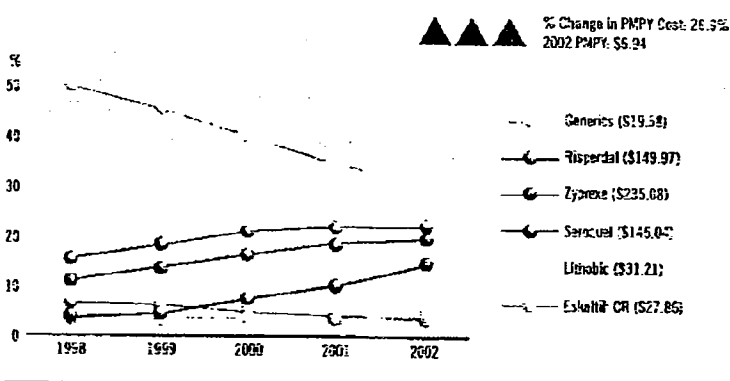


- PMPY costs for antianxiety drugs grew by a scant 1.6 percent to \$6.44 in 2002, despite a 5 percent increase in utilization. The key reason for this minimal cost change was the availability of generic BuSpar® (buspirone). As a consequence, the wider use of generics in this class brought the cost per prescription down 3.3 percent.
- The generic fill rate in this class increased from 89.7 percent to 96 percent.
- A drug already approved for treating depression and GAD, Effexor® XR (venlafaxine extended-release), has also been approved for treating social anxiety disorder.
- Results from Phase III studies for the use of Lexapro® (escitalopram) for the treatment of anxiety show significant improvement in the symptoms of GAD among participants who took active drug. Lexapro® is already approved for treating depression.
- Another investigational antianxiety drug, pagoclone, has shown poor results in both Phase II trials for GAD and Phase III testing for panic disorder. Further development is questionable.

### Antipsychotics

Psychoses comprise more serious mental disorders that are characterized by defective contact with reality. Frequently accompanied by delusions and/or hallucinations, psychoses usually interfere with normal social interactions. Psychosis is diagnosed in 0.2 percent to 0.7 percent of Americans.<sup>17</sup>

Figure A4  
Therapy Class Drug Market Share Trend — Antipsychotics



17 Kendler KS, Gallagher TL, Abelson JV, Kessler RC. Lifetime prevalence, demographic risk factors, and diagnostic validity of affective psychosis as assessed in a US community sample. *Archives of General Psychiatry*. 1996; 53:1022-1031.

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PMPY costs for antipsychotics grew 26.9 percent to \$6.94; 59.9 percent of this increase was due to rising per prescription costs.

About two-thirds of the increase in per prescription costs was due to mix change, as the market shares of the expensive products Zyprexa® (olanzapine), Seroquel® (quetiapine) and Geodon® (ziprasidone) increased.

In November 2002, the FDA approved a new antipsychotic medication, Abilify® (aripiprazole), for the treatment of schizophrenia. A dopamine system stabilizer, Abilify® is taken once a day.

#### *Future Trends*

Phase III trials continue for Zomaril™ (iloperidone), a serotonin/dopamine receptor antagonist (SDA) for the treatment of schizophrenia and related psychotic disorders. A second SDA, Org 5222, entered Phase III trials for schizophrenia in November 2002.

## PAIN/INFLAMMATION

Acute pain is temporary. It can follow surgery, an injury, burns or dental procedures. Nearly everyone has episodes of acute pain sometime during a year.

Chronic pain — generally accepted as pain that lasts more than 3 months — often is associated with malignant conditions, but non-cancer-related pain affects many more people of all ages. According to the American Chronic Pain Association, approximately 50 million people in this country have some degree of chronic pain.<sup>18</sup> Frequently, chronic pain is complicated by depression, disability, difficulty walking and trouble sleeping.

One of the most common causes of chronic pain is arthritis — a broad term for over a hundred conditions that produce pain, swelling and stiffness in the body's support structures. Primarily, arthritis attacks joints, but it also damages bones, ligaments, muscles, tendons and even internal organs, in some cases. The Centers for Disease Control and Prevention estimate that arthritis affects nearly 70 million people in the U.S.<sup>19</sup> Osteoarthritis (OA) is the most prevalent form with an estimated 20 million victims in the United States. Often attributed to "wear-and-tear" on the joints, OA affects at least half of people who are 65 or older and around 80 percent of people over the age of 80.<sup>20</sup> In addition, approximately 2 million American adults have rheumatoid arthritis (RA), an autoimmune condition.<sup>21</sup> Children get arthritis, too — around 285,000 Americans develop arthritis symptoms before the age of 16.<sup>22</sup> Other forms of arthritis include carpal tunnel syndrome, fibromyalgia, gout, lupus and Lyme disease.

Injury to peripheral nerves causes neuropathic pain. One of the biggest contributors is diabetes, with an estimated 2.6 million Americans having moderate-to-severe neuropathic pain related to diabetes.<sup>23</sup>

- Late in December, the FDA approved Humira™ (adalimumab, D2E7) as monotherapy or in combination with other drugs for moderate-to-severe RA. Self-injected subcutaneously once every 14 days, Humira™ is a monoclonal antibody that inhibits a tumor necrosis factor (TNF-alpha).
- The maker of Enbrel® (etanercept) has requested a new indication for ankylosing spondylitis, a degenerative disease of the spine that is believed to affect as many as a million people in the United States.<sup>24</sup> Currently approved as a twice-weekly injection, Enbrel® is also in Phase III studies for a once-weekly dosage form.

18 American Chronic Pain Association. Pain fact sheet. No Date Given. Available at: [http://www.theacpa.org/pain\\_fact\\_sheet.asp](http://www.theacpa.org/pain_fact_sheet.asp). Accessed January 28, 2003.

19 Centers for Disease Control and Prevention. Prevalence of self-reported arthritis or chronic joint symptoms among adults - United States, 2001. *Morbidity and Mortality Weekly*. 2002;51(42):949-952.

20 National Institute of Arthritis and Musculoskeletal and Skin Diseases. National Institutes of Health. Headout on health: csa-arthritis. July 2002. Available at: <http://www.niams.nih.gov/hi/topics/arthritis/csaheadout.htm#2>. Accessed January 28, 2003.

21 National Institute of Arthritis and Musculoskeletal and Skin Diseases. National Institutes of Health. Headout on health: rheumatic arthritis. Revised November 1999. Available at: <http://www.niams.nih.gov/hi/topics/arthritis/rheadout.htm>. Accessed January 28, 2003.

22 American College of Rheumatology. Juvenile arthritis. 2000. Available at: <http://www.rheumatology.org/patients/factsheet/jra.html>. Accessed January 28, 2003.

23 Dyck PJ, Kretz RM, Kames ... et al. The prevalence by staged severity of various types of diabetic neuropathy, retinopathy, and nephropathy in a population-based cohort. The Rochester Diabetic Neuropathy Study. *Neurology*. 1993;43:817-824.

24 Spondylitis Association of America. What is spondylitis? fact sheet. Available at: <http://www.spondylitis.org/html/htmlpages.asp?1056-whatissas.htm>. Accessed January 28, 2003.

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### Key Trends

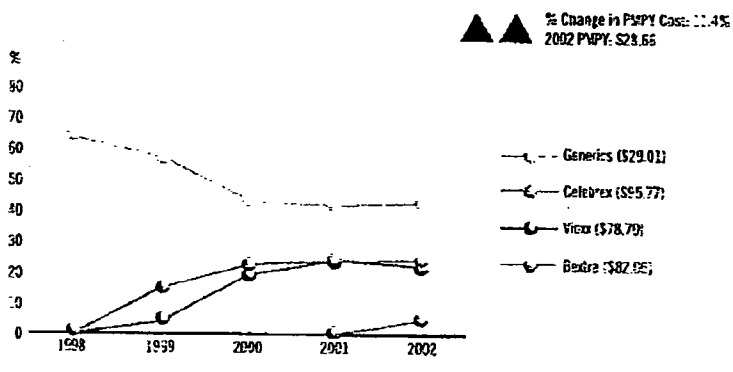
- Results of Phase II trials for pralnacasan (HMR3480/VX-740) show promise that it has anti-inflammatory effects for people with RA. Pralnacasan, the first in its class, is an oral interleukin-1 beta converting enzyme (ICE) inhibitor.
- A variation of acetaminophen that has been changed so that it releases nitric oxide has entered Phase II testing in the United States. The drug — presently called NCX 701 — is anti-inflammatory as well as analgesic. Nitric oxide, a biologically active compound, is thought to protect against stomach irritation. A similar variation on naproxen, AZD3582, showed pain control in Phase II tests, but it did not appear to protect stomach tissue. A nitric oxide-donating aspirin is in earlier stages of study.
- Paxceed™ (micellar paclitaxel for injection) is in Phase II trials for treating rheumatoid arthritis. It is formulated to need injecting only once a month.
- Phase II studies have finished for CNS 5161 in the treatment of neuropathic pain. Given intravenously, CNS 5161 belongs to a new class of drugs that block N-methyl-D-aspartate (NMDA) ion channels.
- A synthetic derived from carboxylic tetrahydrocannabinol is early in European Phase II study for chronic neuropathic pain. Designated as CT-3 (ajulemic acid) the compound does not appear to affect mental processes like its parent compound does.

### Anti-Rheum (NSAIDs)

Non-steroidal anti-inflammatory agents (NSAIDs) are used in the treatment of all kinds of pain. Many brands and generics are available without prescription. Generics are available for many of the most widely-prescribed prescription products.

Figure A5

Therapy Class Drug Market Share Trend — Anti-Rheum (NSAIDs)



- NSAIDs had the fifth highest PMPY costs in 2002, \$28.66.
- PMPY NSAIDs costs rose 11.4 percent in 2002. About one-half of this growth was due to higher utilization, including the use of Bextra®, a new COX-2 brought to market in 2002. COX-2s, Celebrex®, Vioxx® and Bextra®, now comprise 50.6 percent of the NSAIDs market.
- A generic for Lodine® XL, etodolac, extended-release, was approved in July 2002.
- Vioxx® (rofecoxib) received an additional indication for treating RA.
- While reports questioned the cost-effectiveness of COX-2 inhibitors, the makers of COX-2s currently on the U.S. market were required to make labeling changes. In April 2002, the FDA allowed the Vioxx® label to report a more positive gastrointestinal side effect risk, but a warning for people with cardiovascular disease and hypertension was also required to be added. In June, the manufacturer of Celebrex® (celecoxib) had to keep a warning about the potential for stomach damage on the product labeling. In November, Bextra® (valdecoxib) labeling had to be revised to include information on rare but potentially dangerous hypersensitivity reactions.

#### *Future Trends*

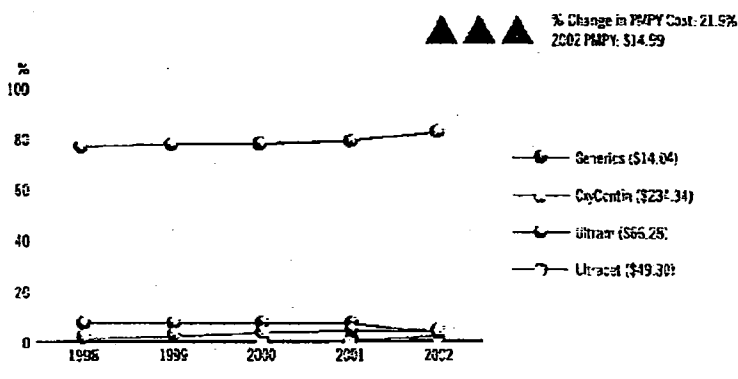
- In November 2002, an NDA was filed for the approval of Prexige® (lumiracoxib) after extensive clinical trials compared it to already approved COX-2 inhibitors.
- The NDA for another COX-2, Arcoxia™ (etoricoxib) has been withdrawn temporarily while the manufacturer conducts more trials of its cardiovascular safety and its effectiveness in treating chronic pain. Arcoxia™ is already approved in Europe for OA, RA, acute pain and chronic back pain.
- Dynastat® (parecoxib for injection) has been approved in the European Union for treating short-term pain after surgery. The only injectable COX-2 to date, Dynastat®, has not yet been submitted for FDA approval.

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**Narcotic Analgesics**

Usually reserved for intense or unremitting pain, narcotics have the potential for addiction and/or abuse.

Figure A5  
Therapy Class Drug Market Share Trend — Narcotic Analgesics



- The costs of Narcotic Analgesics grew by 21.9 percent to \$14.99 in 2002. This continues a trend of substantial increases seen in this class over the past five years.
- This increase was due almost equally to higher utilization and cost per prescription. The increase in the cost per prescription occurred despite the availability of tramadol, the generic of Ultram®, in the summer.
- The generic fill rate in the class grew to 81.9 percent.
- Although Phase III trial results were positive, research for Dirame® (propiram), a novel narcotic, has been stopped after the manufacturer reassessed its potential.

**Future Prospects**

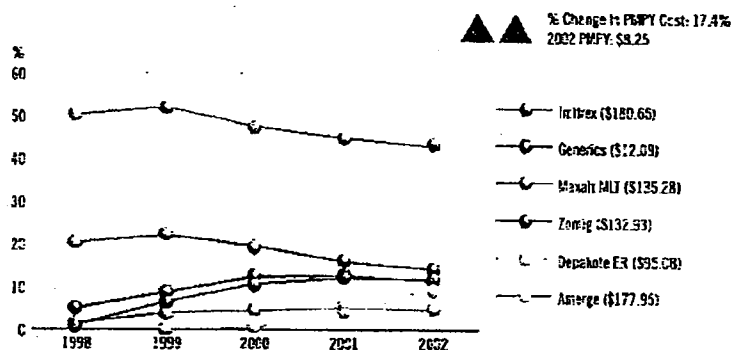
- A modification of oxycodone, OxyTrex™, is in Phase III testing for the pain of OA. The company testing it is also studying a morphine product, MorViva™. Both are formulated to limit potential abuse.
- An extended-release form of tramadol designed to be taken only once a day has finished Phase III trials in the United States. If approved, it will be indicated for OA.

- Phase III trials are planned for an intranasal form of ketamine. Under study for moderate-to-severe acute pain and exacerbations of chronic pain, ketamine is currently approved for general anesthesia. A topical combination product that includes ketamine and amitriptyline is in Phase II testing for neuropathic pain.
- Also entering Phase III trials is a morphine derivative, morphine-6-glucuronide (M6G). To be used for severe pain, M6G will be administered through a unique type of patch system. A morphine formulation that would be administered intranasally is earlier in the development process for the relief of breakthrough pain in cancer patients.

### Migraine Products

Up to 18 percent of women and 6 percent of men — between 25 million and 30 million people in the United States — will experience at least one migraine headache during their lifetimes. Unlike most health conditions, migraine headaches show an inverse relationship to age. Among 18 to 44 year olds, the incidence of migraine is about 19 percent. In the 65 to 74 year age bracket, however, incidence declines to about 8 percent.<sup>25</sup>

Figure A7  
Therapy Class Drug Market Share Trend — Migraine Products



- PMFPY ingredient costs for the migraine class grew by 17.4 percent to \$8.25. Most of this increase was due to higher utilization, primarily from higher prevalence rates.
- Despite losing market to Depakote® ER, Imitrex® continued to hold the largest market in the class at 42.8 percent.

<sup>25</sup> American Council on Headache Education. What you should know about headache. Last modified January 9, 2001. Available at: <http://www.ache.net.org/understanding>. Accessed January 28, 2003.

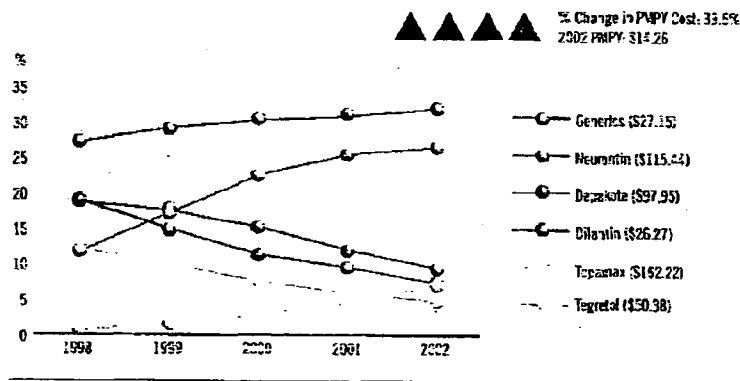
- The generic fill rate in this class continued to decline, dropping to 14.1 percent in 2002.
- Relpax® (eletriptan) received FDA approval in December 2002.
- Botox® (botulinum toxin type A) is being used to prevent migraines, even though it is not FDA-approved for use in headache treatment.
- The NDA for MT300, a self-injectable form of dihydroergotamina, was submitted for the FDA's review in December 2002.
- Results are pending from Phase III trials of an investigational migraine product designated MT 100. An oral compound, MT 100 combines metoclopramide and naproxen.

### Anticonvulsants

Active epilepsy is defined as either having at least one seizure event in recent years or being on anticonvulsant medication. The Epilepsy Foundation of America estimates that about 2.3 million U.S. citizens have diagnosed epilepsy — including about 300,000 children under the age of 15 and about 550,000 people over the age of 64. Approximately 60 percent of people with epilepsy have only one seizure; another 15 percent have more than one, but seizures eventually stop. Seizures will persist for around 25 percent of people who have an epilepsy diagnosis.<sup>25</sup>

Figure A3

Therapy Class Drug Market Share Trend — Anticonvulsants



25. Epilepsy Foundation of America. *Epilepsy: a report to the nation*. 1999. Available at: <http://www.epilepsyfoundation.org/usa/nation/nation.html>. Accessed September 14, 2002.



- The PMPY costs for anticonvulsants grew faster than those of any of the other top 25 classes. Growing by one-third, the 2002 PMPY cost of this class reached \$14.26.
- This substantial cost increase was about equally attributable to greater use and higher per prescription costs. Virtually all of the increased use was due to more people using these products, probably to treat pain. Inflation and use of more expensive products in the class — Neurontin®, Topamax®, Lamictal® and Trileptal® among others, were the prime reasons for the increase in per prescription costs.
- Neurontin® (gabapentin) received an additional indication for the treatment of post-herpetic neuralgia, the nerve pain that frequently follows shingles.
- Gabapentin capsules, the generic equivalent of Neurontin® capsules, were approved by the FDA in January 2003. Marketing of the generic is delayed due to litigation.
- A once-daily formulation of Depakote® (divalproex extended-release) was approved in December 2002.
- The filing of an NDA for pregabalin was delayed while additional testing was conducted. The manufacturer will likely seek indications for neuropathic pain and generalized anxiety disorder, as well as for epilepsy.
- After Phase III studies indicated that Topamax® (topiramate), a medication approved for treating seizures, was successful for preventing migraines, its manufacturer filed for that new indication late last year. Studies of Topamax® as an anti-obesity agent are on hold while the company reformulates it. Topamax® failed to show significant effectiveness against neuropathic pain, however, so studies into that indication have been discontinued.
- The maker of another anticonvulsant, Lamictal® (lamotrigine), has asked the FDA for an additional indication in treating bipolar disorder. In clinical studies, Lamictal® proved significantly better than placebo in delaying depressive episodes among more than 600 adults with bipolar disorder.

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## CARDIOVASCULAR

The American Heart Association estimates that nearly 62 million Americans — more than half of them under the age of 65 years — suffer from some form of cardiovascular disease. Responsible for over 39 percent of all deaths in 2000, heart disease is the number one cause of death in the United States.<sup>27</sup> Beginning in 1984, more women than men have died from heart diseases each year.<sup>28</sup> The incidence of heart conditions rises with age, and people who have conditions such as diabetes and obesity are more likely to have heart disease as well.

Many people have more than one heart condition, including approximately:

- 50.0 million having high blood pressure
- 12.9 million with coronary heart disease (CHD)
- 6.6 million who have angina
- 4.9 million having congestive heart failure (CHF)
- 4.7 million stroke victims<sup>29</sup>

Millions more have arrhythmias, atherosclerosis, peripheral arterial disease and other less common heart-related conditions. About 40,000 of the children born in this country each year have some degree of congenital cardiovascular defect.<sup>30</sup>

In December 2002, results were released from ALLHAT (Antihypertensive and Lipid-Lowering Treatment to Prevent Heart Attack Trial). In the long-term study that began with more than 42,000 patients who had hypertension and at least one other risk factor for heart disease, treatment with the diuretic chlorthalidone was generally more effective in controlling blood pressure and reducing the risk of cardiovascular events than a calcium channel blocker (Norvasc® [amlodipine]) or an ACE inhibitor (Prinivil® [lisinopril]). A portion of the study involving an alpha-blocker, Cardura® (doxazosin), was terminated early after participants taking it had higher rates of cardiovascular events than those taking the diuretic. While the study sponsors recommend beginning treatment for hypertension with a diuretic, they also found that most patients needed additional therapy with another class of antihypertensive as well.

A study published in February, however, found that ACE inhibitors and diuretics work equally well to lower blood pressure for elderly patients. In the Second Australian National Blood Pressure Study (ANBP2) patients taking diuretics had more fatal and non-fatal cardiac events than those on an ACE inhibitor. The results of ANBP2 and ALLHAT are not comparable because each study used different approaches to treatment and the participants in each study had different characteristics. In addition, all the results need further interpretation.

27 American Heart Association, Heart disease and stroke statistics — 2003 update, Dallas, TX: American Heart Association; 2002.

28 American Heart Association, Women and cardiovascular diseases, 2002. Available at: <http://www.americanheart.org/downloadable/heart/109997177381510WASZWEB.pdf>. Accessed January 20, 2003.

29 American Heart Association, Heart disease and stroke statistics — 2003 update, Dallas, TX: American Heart Association; 2002.

30 American Heart Association, Heart disease and stroke statistics — 2003 update, Dallas, TX: American Heart Association; 2002.

In late September 2002, the FDA granted approval for Inspra® (eplerenone), a selective aldosterone receptor blocker, for treating hypertension. Further testing continues for the drug's effectiveness in treating heart failure that follows a heart attack.

#### Future

- Phase III trials have begun for sitaxsentan, an endothelin blocker to treat pulmonary hypertension (PH). PH is a relatively uncommon but extremely serious condition in which high blood pressure in the artery between the right side of the heart and the lungs may result in heart failure. Sitaxsentan is also under study for CHF and general hypertension.
- In October 2002, an FDA advisory committee dealt another setback for Vanlev® (omapatrilat) when it recommended further clinical testing for the vasoactive inhibitor. Although Vanlev® appears to be effective in treating hypertension, it also seems to have significant safety issues. It may be resubmitted after it is tested in patients with hypertension that resists treatment with maximal doses of other medications.
- An NDA was submitted in December 2002 for Ranexa™ (ranolazine) as a treatment for chronic angina. Ranexa™ is the first in a new class called pFOX inhibitors that partly inhibit the oxidation of fatty acids.
- In a Phase III clinical trial, the selective A1-adenosine receptor agonist called tecadenoson (CVT-510) showed promise for patients with paroxysmal supraventricular tachycardia (PSVT), an abnormally rapid heart rhythm. Tecadenoson is in Phase IIb tests for atrial fibrillation.
- Liprostin™ (liposomal prostaglandin E1) is in Phase III trials for critical limb ischemia — severely diminished circulation that may result in lower extremity amputation. In addition, Liprostin™ may also prevent reblocking of arteries after angioplasty or bypass surgery.
- One angiogenesis drug, Angiogenix™, has begun Phase III trials for myocardial ischemia and angina. It is in a new class of nicotinic acetylcholine receptor (AChR) agonists that are derivatives of nicotine. Drugs in the class promote the growth of new blood vessels. Other angiogenesis drugs are in earlier stages of development for several types of cardiovascular conditions.
- Simultaneous Phase II trials are being conducted for a drug that breaks structural connections in advanced glycosylation end-products (AGEs). The drug, currently known as ALI-711, is under study for hypertension and different types of heart failure.
- ECT 588, a unique injectable product is in several Phase II trials for atherosclerosis. ECT 588 is a large unilamellar vesicle (LUV) product derived from natural lipids that help reduce the cholesterol portion of atherosclerotic plaques.

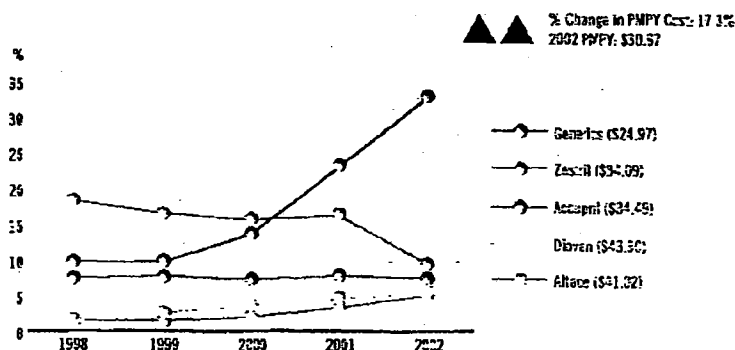
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### Antihypertensives

In addition to treating high blood pressure, drugs in the antihypertensives group can be used for CHF, post-myocardial infarction, left ventricular dysfunction and diabetic nephropathy.

Figure A9

Therapy Class Drug Market Share Trend — Antihypertensives



- Antihypertensives continue to be the most widely used class of drugs at 0.86 prescriptions PMPY, although they represent the fourth most expensive class.
- The PMPY costs for this class grew by 17.3 percent to \$30.97 in 2002. About two-thirds of this increase was due to high utilization, mostly due to more people using these drugs.
- The FDA approved lisinopril — the generic for ACE inhibitors (ACEIs) Prinivil® and Zestril® — and lisinopril and hydrochlorothiazide — the generic for Prinzip® and Zestoretic® in July 2002. Several manufacturers began marketing the generics almost immediately.
- The availability of lisinopril helped overcome the 7.6 percent rise in inflation and the 3.2 percent mix increase from greater use of more expensive ARBs. Although not on the market until July 2002, lisinopril still managed to capture an annual 8.4 percent market share in the class.
- The overall generic fill rate in this class rose from 23.2 percent in 2001 to 32.9 percent in 2002.
- The NDA for a new angiotensin II receptor blocker (ARB), Benicar™ (olmesartan), was approved by the FDA in April 2002. Benicar™ can be used alone or with other antihypertensives to treat high blood pressure.
- In the summer of 2002 another ARB, Diovan® (valsartan), received a new indication for treating heart failure in patients who cannot take ACE inhibitors.

- In early 2003 an FDA advisory committee recommended approval for a new indication in reducing cardiovascular morbidity and mortality for Cozaar\* (losartan), another ARB.
- The combination product Tevetan\* HCT (eprosartan and hydrochlorothiazide) was approved for the treatment of hypertension in February 2003.

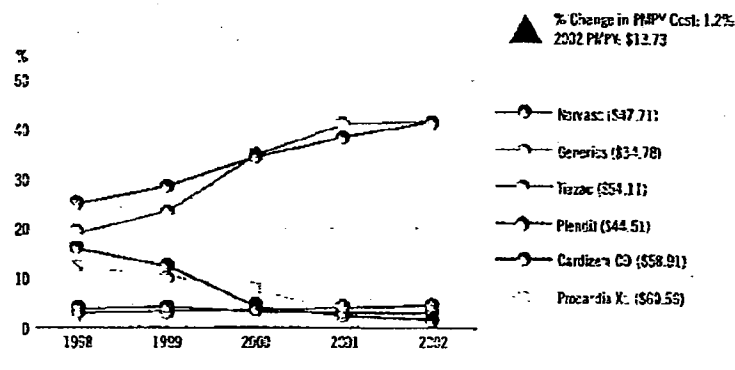
#### Future Trends

- Two ACEIs, Accupril\* (quinapril) and Monopril\* (fosinopril), are slated to lose their patents in 2003.

#### Calcium Blockers

The main indications for calcium blocking drugs are angina, arrhythmias and hypertension.

Figure A10  
Therapy Class Drug Market Share Trend — Calcium Blockers



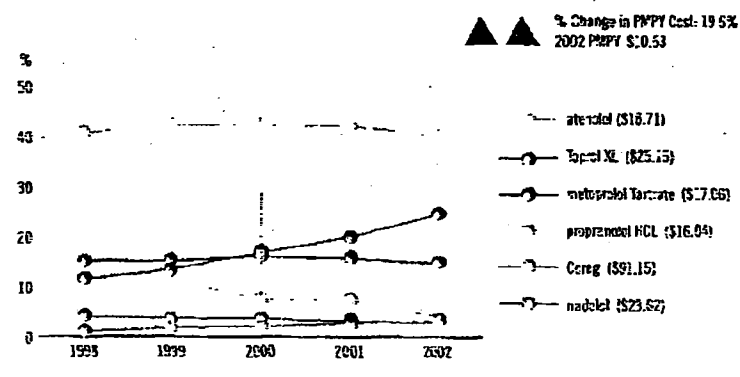
- PMPY costs for calcium channel blockers rose by a scant 1.2 percent to \$13.73. Following a trend seen in recent years, utilization of drugs in this class continues to erode.
- The NDA for a new calcium blocker, lercanidipine, was found "approvable" by the FDA in August 2002. However, the FDA requested additional studies to verify dosing for the once-daily treatment for hypertension. Final approval is likely to be delayed by 2 to 3 years.

### Beta Blockers

Drugs that block beta receptors are used widely for cardiovascular problems — primarily hypertension, CHF and post-myocardial infarction. Some have additional indications in non-cardiac conditions such as preventing migraine headaches and controlling tremors.

Figure A-2

Therapy Class Drug Market Share Trend — Beta Blockers



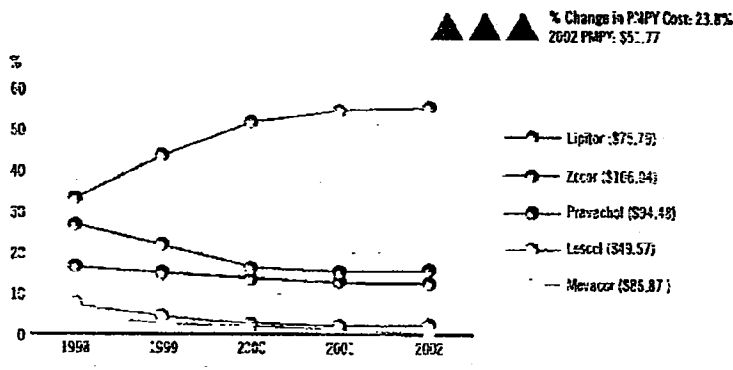
• Beta blockers continue to be the eighth most widely used of the top 25 classes. The 2002 PMPY cost of this heavily generic class rose by 19.6 percent to \$10.53. Roughly equal portions of this growth are attributable to utilization and per prescription increases.

• In January 2003 an FDA advisory committee recommended a new indication be approved for Coreg® (carvedilol) in the reduction of mortality following heart attacks in patients who have left ventricular dysfunction.

### Antihyperlipidemics

The American Heart Association estimates that approximately 105 million Americans over the age of 19 years have total cholesterol (TC) levels above 200mg/dL — levels that put them at increased risk for heart disease. Additionally, around 10 percent of adolescents in this country are also above the 200mg/dL threshold. About 40 million U.S. citizens exceed 240mg/dL for TC — putting them at approximately twice the risk of developing CHD as a person whose TC is less than 200mg/dL.<sup>31</sup>

Figure A12  
Therapy Class Drug Market Share Trend — Antihyperlipidemics



- In 2002 antihyperlipidemics surpassed antidepressants as the second most expensive therapy class. PMPY costs for this class rose by 23.8 percent to \$51.77. About 60 percent of this rise was due to greater utilization due to more people using these types of drugs.
- Lipitor® continues to dominate this class with a 55.4 percent market share.
- The first cholesterol absorption inhibitor, Zetia® (ezetimibe), was approved in October 2002 and was available in December 2002. The once-daily drug can be used as monotherapy or in combination with a statin.
- Some statins have been approved for familial hypercholesterolemia patients between the ages of 10 years and 17 years. Mevacor® (lovastatin) was given the pediatric indication in February 2002 followed by Pravachol® (pravastatin) in October and Lipitor® (atorvastatin) in November 2002.
- After finding the new statin, Crestor® (rosuvastatin) "approvable" in June 2002, the FDA requested more information on its safety profile. Additional data were submitted in February 2003.

31 American Heart Association, Heart disease and stroke statistics — 2003 update. Dallas, TX: American Heart Association; 2002.

Appendix B	Appendix A	Actions	Specialty Injectables	Cost Forecast	Trends in Expenditures	Introduction	Preface	Table of Contents
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- Altacor™ (lovastatin, extended-release) was approved in the second quarter of 2002.
- A generic equivalent for Tricor® (fenofibrate) has received approval from the FDA. Fenofibrate is indicated for the treatment of high triglyceride levels. Also receiving tentative approval is a generic for Pravachol®, even though patent protection for the brand-name product does not expire until 2005.

#### *Future Trends*

- Phase II trials are under way for two immune regulating hormones. HE 2200 and HE2500 are being studied for the treatment of hypercholesterolemia and hypertriglyceridemia, respectively.
- Also in Phase II development is a vaccine called CETi-1. In a series of four injections, CETi-1 aims to raise levels of high density lipoproteins (HDL) by inhibiting cholesterol's transfer from HDL to LDL. At least two similar compounds are in European development.
- Clinical trials continue for avasimibe, an oral selective inhibitor of acyl-coenzyme A-cholesterol acyltransferase (ACAT). Avasimibe and drugs like it may limit the storage of cholesterol as atherosclerotic plaques.
- Although it has been filed for approval in Japan, pitavastatin remains in Phase II testing in the United States and Europe.



## RESPIRATORY

Based on information from the National Health Interview Survey, the American Lung Association estimates that approximately 8.8 million Americans have chronic bronchitis and 2.8 million have emphysema. Most of the people who have these chronic obstructive pulmonary diseases (COPD) are over the age of 45 years, and many are smokers.<sup>32</sup>

- In September 2002, an FDA advisory committee recommended the approval of Spiriva<sup>®</sup> (tiotropium powder for inhalation) for treating COPD-associated bronchospasm. If it is approved, Spiriva<sup>®</sup> will be used once a day through a dry powder inhalation system.
- Roflumilast, an oral agent that selectively inhibits phosphodiesterase-4 (PDE-4) is in Phase III trials for both asthma and COPD. Another oral PDE-4 inhibitor, Arlio<sup>®</sup> (cilomilast), continues Phase III trials in the United States.

Another respiratory condition that affects a smaller population in the United States is cystic fibrosis (CF), a genetic disease that causes mucus to become thick and sticky. The 30,000 U.S. residents with CF<sup>33</sup> — mostly children and adolescents — are prone to lung infections because bacteria get trapped in lung tissue, where antibiotics cannot penetrate well.

- In November 2002, a drug for CF gained Orphan status from the FDA. The drug, P1130, is a peptide that appears to fight infections that resist normal antibiotic treatment.
- A second product, Moli 1901 (duramycin) is in U.S. Phase II trials for CF. Already approved as an Orphan drug in the European Union, Moli 1901 may help to return the mucus in the lungs of CF patients to a more normal consistency.
- Also in Phase II testing is NCX 950, a salt of albuterol that has been modified to donate nitric oxide. In early studies, NCX 950 has shown both anti-inflammatory and bronchodilatory effects. Phase II trials are also being conducted for DCF 987, an inhaled dextran derivative that appears to keep bacteria from implanting in lung tissue and also to help thin mucus in CF patients.

32 American Lung Association Epidemiology and Statistics Unit. Trends in chronic bronchitis and emphysema: morbidity and mortality. American Lung Association. March 2002. Available at: <http://www.lungusa.org/data/ea1/COPD1.pdf>. Accessed January 6, 2003.

33 Cystic Fibrosis Foundation. About cystic fibrosis. What is cystic fibrosis? N: Date Given. Available at: [http://www.cff.org/about\\_c/what\\_is\\_cf.cfm?CFID=598553&CFTOKEN=53399282](http://www.cff.org/about_c/what_is_cf.cfm?CFID=598553&CFTOKEN=53399282). Accessed January 29, 2003.

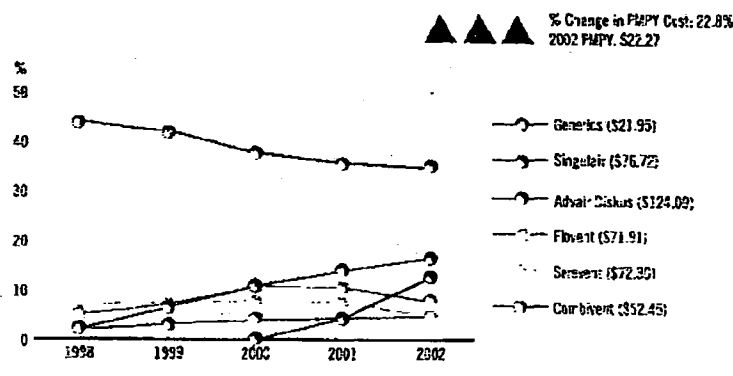
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### Antiasthmatics

Asthma affects almost 25 million Americans, with about 8 million under the age of 18 and approximately 2 million over the age of 64. Between 40 percent and 75 percent of people with asthma will have at least one sinus infection per year.<sup>34</sup>

Figure A13

Therapy Class Drug Market Share Trend — Antiasthmatics



- PMPY costs for antiasthmatics increased by 22.8 percent to \$22.27 in 2002. Similar to the case in 2001, the principal reason for this growth was higher costs per prescription, not higher utilization rates. The use of more expensive products in this class — mix — is the primary driver in the cost per prescription increase. The market share growth — from 4.3 percent to 12.6 percent — for the relatively expensive product Advair Diskus<sup>®</sup> and the 2.6 percentage point market share growth for Singulair<sup>®</sup> accounted for most of this mix growth.
- In June 2002, updated guidelines for treating asthma were issued by an expert panel of the National Asthma Education and Prevention Program. Among their recommendations was new evidence that appropriate doses of inhaled corticosteroids (ICs) are safe for use in children. The updates re-emphasized that ICs are the treatment of choice for asthma's underlying inflammation.
- In December, new information was filed with the FDA for the anti-IgE monoclonal antibody Xolair<sup>®</sup> (omalizumab). Additional evidence on the drug had been requested by an FDA advisory committee in July 2001.
- A large post-marketing study of Serevent<sup>®</sup> (salmeterol) was stopped after a rare but increased risk of life-threatening events was reported in some study participants. The FDA and the drug's manufacturer are evaluating the study for possible further action.

<sup>34</sup> American Lung Association Epidemiology and Statistics Unit. Trends in asthma morbidity and mortality. American Lung Association, February 2002. Available at: <http://www.lungusa.org/ce/asthma/asthma1.pdf>. Accessed January 6, 2003.

Asmanex<sup>®</sup>

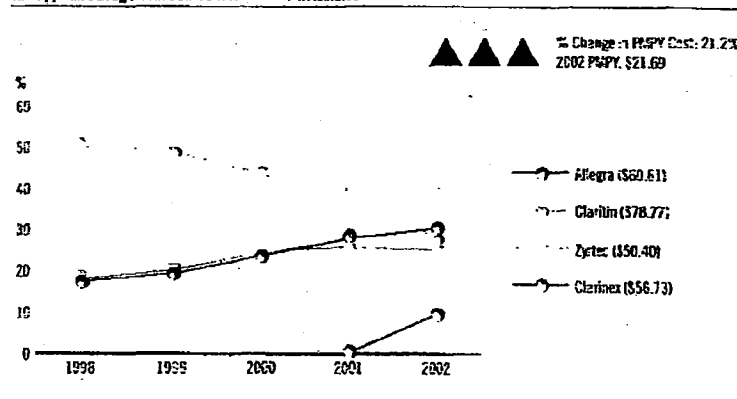
- Asmanex<sup>®</sup> (mometasone dry powder inhaler), a once-daily corticosteroid, was marketed in the European Union early in 2003 while it was still under review by the FDA.
- Phase III trials continue for ciclesonide, a corticosteroid under study as a once-daily oral inhalation for asthma or nasal spray for allergic rhinitis.

### Antihistamines

An estimated 40 million to 50 million Americans suffer from allergic conditions. By far the most common is "hay fever" caused by pollens and other airborne irritants.<sup>35</sup> These respiratory allergies affect 9 percent to 16 percent of the population, depending on the time of year. About 35 million people in the United States have seasonal allergy problems, and millions more suffer with perennial allergies.<sup>36</sup> Allergies to drugs, foods, insect bites, latex and other substances are much less common.

Figure A14

Therapy Class Drug Market Share Trend — Antihistamines



- Similar to the growth rate experienced in 2001, PMPY spending for antihistamines grew by over 21 percent to \$21.69 in 2002. The cost per prescription rose by about 9 percent despite the entry of somewhat less expensive Clarinex<sup>®</sup>. When the use of Clarinex<sup>®</sup> is factored in, utilization of antihistamines grew by about 11 percent.
- Low and non-sedating products — Allegra<sup>®</sup>, Claritin<sup>®</sup>, Clarinex<sup>®</sup> and Zyrtec<sup>®</sup> — commanded over 90 percent of the antihistamine market.

35 American Academy of Asthma Allergy and Immunology. Allergy statistics. No Date Given. Available at: [http://www.aaaai.org/media/resources/media\\_allergy\\_statistics.stm](http://www.aaaai.org/media/resources/media_allergy_statistics.stm). Accessed September 9, 2002.

36 National Institute of Allergy and Infectious Disease. National Institutes of Health. Fact sheet: allergy statistics. January 2002. Available at: <http://www.niaid.nih.gov/factsheets/allergystat.htm>. Accessed December 3, 2002.

- In mid-December 2002, Claritin® (loratadine) switched from prescription to over-the-counter (OTC) status. Because of its late market entry, most plan sponsors made no change in coverage or copayment rules for this class. Also in December, approval was granted for OTC sale of Alavert®, an instantly-disintegrating formulation of loratadine.

- An asthma drug, Singulair® (montelukast), received FDA approval for a new indication — treating symptoms of seasonal allergic rhinitis. An oral leukotriene receptor blocker, Singulair®, is approved for allergies in adults and children 2 years old and older.

#### Future Plans:

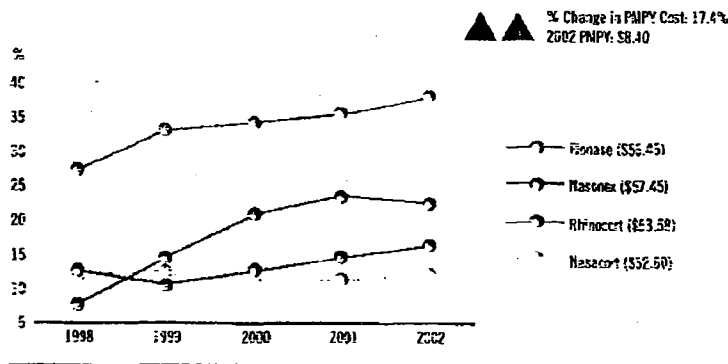
- In November 2002, Phase III testing began for a new intranasal product to be used for nasal allergy symptoms. Called INS37217 Intranasal, the product activates P2Y2 receptors on airway mucosa. It is also being studied for use in other respiratory conditions.
- The NDA for Soltara® (tecaterizole) may be resubmitted with additional information from supplemental trials. An FDA advisory committee found the original NDA “not approvable” in March 2002.

#### Decongestants/Nasal Steroids

Nasally-inhaled steroids are used mainly to treat allergies. They act as local decongestants to relieve swollen nasal and sinus tissue.

Figure A15

Therapy Class Drug Market Share Trend — Decongestants/Nasal Steroids

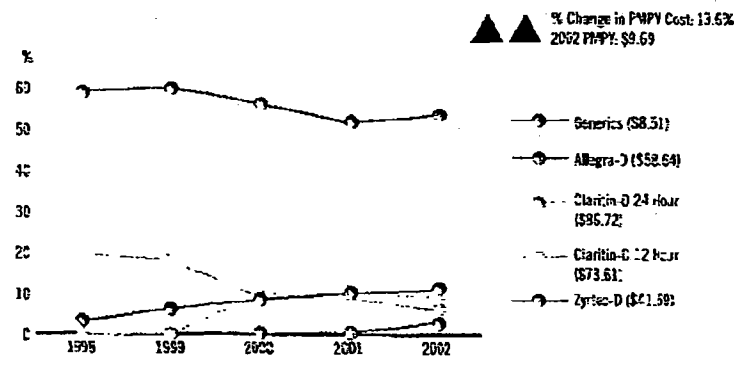


- PMPY ingredient costs for decongestants grew by 17.4 percent. Three-fourths of this increase was due to rising costs, virtually all of which was driven by inflation growth.
- Flonase<sup>®</sup> and Nasonex<sup>®</sup>, nasal steroids, grew their combined market share slightly to about 60 percent.
- Nasonex<sup>®</sup> (mometasone) was given an additional indication for treating allergy symptoms in children as young as 2 years old. It was previously indicated for children over the age of 3 years.

### Cough/Cold

Almost everyone gets a cold sometime during an average year. Because adult immune systems usually have encountered sufficient types of viruses to develop immunity, children have about two or three times as many colds as adults. During 1996, about 30 million cases of acute respiratory infections (other than colds) were reported to the National Center for Health Statistics. In addition, Americans experienced slightly over 95 million cases of the flu and nearly 5 million cases of pneumonia.<sup>37</sup> Coughing is a symptom associated with many respiratory conditions.

Figure A16  
Therapy Class Drug Market Share Trend — Cough/Cold



- Driven by a 13.5 percent inflation rate, PMPY costs for the heavily generic cough and cold class rose to \$9.69, an increase of 13.6 percent over 2001 levels.
- Allegra-D<sup>®</sup>, Claritin-D<sup>®</sup> and Zyrtec-D<sup>®</sup> saw their combined market grow marginally to 30 percent.

37 American Lung Association Epidemiology and Statistics Unit. Trends in morbidity and mortality pneumonia, influenza and acute respiratory conditions. American Lung Association, September 2002. Available at: <http://www.lungusa.org/cata/svpt...pdf>. Accessed January 6, 2003.

## ANTI-INFECTIVES

Estimating the incidence of bacterial, fungal and protozoal infections is almost impossible. Infectious diseases range from barely noticeable to immediately life-threatening. They can be acute — lasting a few hours or days; chronic — persisting for a lifetime; or latent — lying dormant for years, and then flaring into acute or chronic status. They can affect any part of the body, and they strike people in every age group. The World Health Organization reports that infectious diseases account for more worldwide deaths among children and young adults annually than any other single cause.

Bacterial infections affect almost everyone in this country at some time in the year. Some examples:

- The CDC estimates about 76 million U.S. citizens get food-borne illnesses each year — resulting in about 325,000 hospitalizations and 5,000 deaths.<sup>38</sup>
- In 1997, 16 percent of all U.S. adults over 18 were treated at some time during the year for sinus infections — an estimated 37 million acute cases. Nearly 33 million suffer from chronic sinusitis.<sup>39</sup>
- Tuberculosis (TB), a chronic bacterial infection, is latent in 10 million to 15 million Americans. Approximately 10 percent of them eventually will develop active TB, and about 16,000 new cases of active TB will be reported each year.<sup>40</sup>

About 2 million Americans get an infection while they are in the hospital for some other condition, and about 90,000 of those people die as a result.<sup>41</sup>

Fungal infections range from superficial skin conditions like athlete's foot to often fatal diseases such as extrapulmonary disseminated aspergillosis. Infections caused by fungus are increasing, partly due to an increasing number of people with deficient immune systems.

Parasites that infest humans include intestinal worms as well as agents responsible for systemic diseases such as malaria, sleeping sickness and toxoplasmosis. Although parasitic diseases were relatively infrequent in the United States, increased travel, trade and immigration now make them more common throughout the world.

- In February 2002, the FDA released new rules for antibiotic labeling. Designed to help cut down on the development of antibiotic resistance, the new regulations require antibiotic packaging to include information on appropriate prescribing and use of the medications.

38 The Centers for Disease Control and Prevention, FoodNet surveillance report for 2000. No Date Given. Available at: [http://www.cdc.gov/odnet/annual/2002/2002FoodNet\\_report.pdf](http://www.cdc.gov/odnet/annual/2002/2002FoodNet_report.pdf). Accessed January 6, 2003.

39 National Institute of Allergy and Infectious Diseases, National Institutes of Health. Fact sheet, Sinusitis, April 2002. Available at: <http://www.niaid.nih.gov/factsheets/sinusitis.htm>. Accessed September 14, 2002.

40 National Institute of Allergy and Infectious Diseases, National Institutes of Health. Fact sheet, Tuberculosis, March 2002. Available at: <http://www.niaid.nih.gov/factsheets/tb.htm>. Accessed December 3, 2002.

41 Centers for Disease Control and Prevention. Notice to readers. CDC's campaign to prevent antimicrobial resistance in healthcare settings. *Morbidity and Mortality Weekly Review*, 2002;51(15):543.

- An oral suspension, Alinia® (nitazoxanide) was approved in December 2002 for the treatment of children between one year and 11 years of age who have diarrhea caused by the water parasites *Cryptosporidium* or *Giardia*.

- In May 2002, the FDA granted approval for Vfend® (voriconazole), a triazole antifungal agent for the treatment of relatively rare but extremely serious fungal infections that often strike patients who are immunocompromised by other debilitating conditions. It is available in both oral and injectable forms.

- Invarz® (ertapenem), an antibiotic injected or infused once daily for moderate to severe bacterial infections, was approved by the FDA in January 2002.

#### Drug News

- In December 2002, the maker of Cidecin® (daptomycin for injection) submitted an NDA and requested priority review for the antibiotic, which is the first in a class called lipopeptides. Formulated for once-daily use, Cidecin® will be used for complicated infections in hospitalized patients.

- Several Phase III trials are under way for a semi-synthetic glycopeptide antibiotic called oritavancin. The drug is being developed to treat a number of infection types, including some that have become resistant to other antibiotics.

- Another promising broad-spectrum triazole antifungal, Noxafil® (posaconazole), is in late-stage clinical trials. Being developed for both oral and IV use, Noxafil® will be used for serious systemic infections.

- Yet another triazole, ravuconazole, is in earlier stages of study. To be given orally, it appears to be comparable to existing antifungal agents in its class.

- The second member in a new class of antifungal drugs called echinocandins is in Phase III testing. Anidulafungin (LY303366) is an intravenous drug being developed for invasive fungal infections such as candidiasis. The first member of the class, Cancidas® (caspofungin), was approved in 2001.

- The U.S. launch of another echinocandin antifungal, micafungin, has been delayed due to an FDA request for more information on the drug, which is marketed as Fungard® in Japan.

- Phase III trials continue for a glycolipopeptide antibiotic, ramoplanin. In oral dosing studies, ramoplanin was not absorbed significantly, so it may prove especially useful for treating gastrointestinal infections.

- In October 2002, the FDA found another intestinal tract antibiotic, rifaximin, "approvable" for treating traveler's diarrhea. A derivative of rifamycin, it is also in various phases of testing for other indications such as Crohn's disease.

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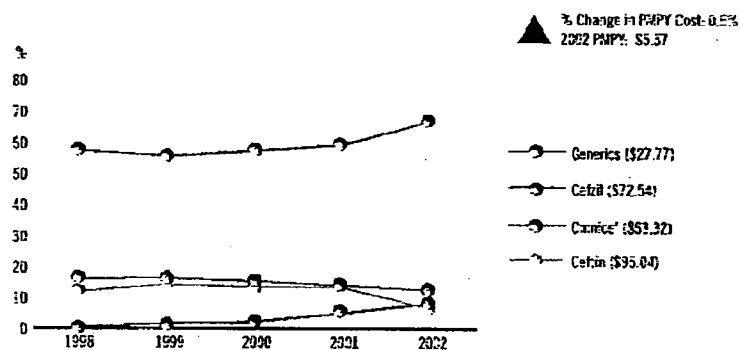
- Phase III clinical trials are being conducted in North America for SYNORB Cd<sup>®</sup>, a synthetic carbohydrate coupled to a biologically inactive silica-based substance. The resulting insoluble compound attaches to bacterial toxins produced by *Clostridium difficile* in the intestinal tract.
- StaphVAX<sup>®</sup> is a vaccine designed to prevent staphylococcal infection in high-risk patients undergoing dialysis or surgery. Its manufacturer projects it will be marketed as early as 2005, pending the result of ongoing clinical trials. Another vaccine, Altastaph<sup>™</sup>, is being developed by the same manufacturer. If approved, it will offer immediate, short-term immunity from staph infection.

### Cephalosporins

Cephalosporin antibiotics are generally broad-spectrum, which means that they are effective against a number of bacteria.

Figure A17

Therapy Class Drug Market Share Trend — Cephalosporins



- The PMPY cost for cephalosporins remained basically flat at \$5.57 in 2001, as it did in 2001. Utilization of these products actually declined by 1.8 percent.
- The production of a third-generation cephalosporin, Suprax<sup>®</sup> (cefixime), was discontinued by the manufacturer for business reasons in July 2002.
- Cefactor<sup>®</sup> extended-release, a generic for Cefcor<sup>®</sup> CD, was approved in September 2002.

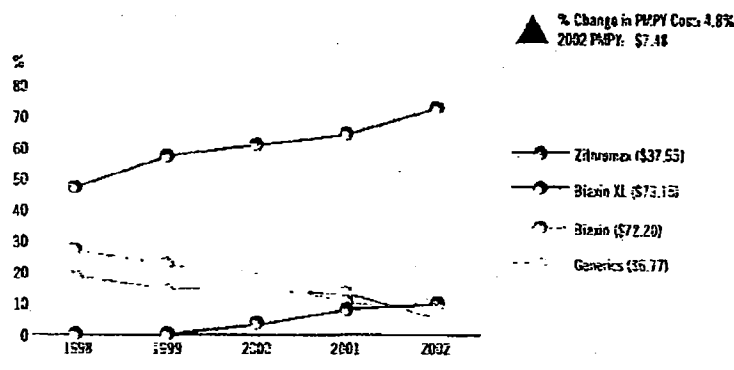


### Macrolides

In general, macrolide antibiotics are safe and effective for infections caused by a number of different bacteria — especially for patients with penicillin allergy. Newer ones, such as Biaxin® (clarithromycin) and Zithromax® (azithromycin) have indications for preventing and treating mycobacterial infections in AIDS patients.

Figure A18

Therapy Class Drug Market Share Trend — Macrolides



2002 PMPY costs for macrolides went up 4.8 percent to \$7.48. Virtually the entire amount of this increase was due to increase in price.

- Zithromax® continued its dominance in this class, increasing its market share to 72.5 percent.

#### Future Developments

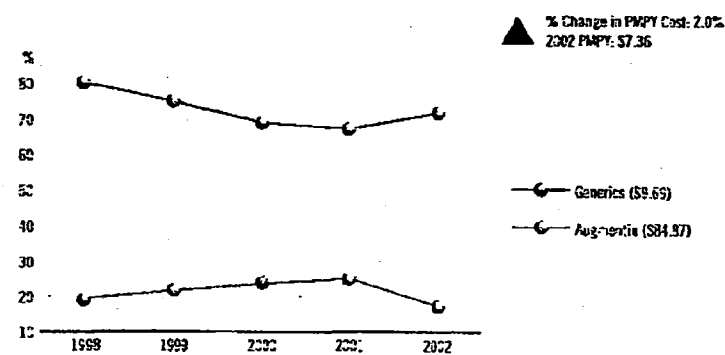
- After the manufacturer submitted additional information on cardiac and hepatic safety, the FDA has found Ketek® (telithromycin) "approvable," pending the submission of further analysis. No additional studies are required. Ketek® is the first of a new type of macrolides called ketolides, which will be used for respiratory infections that are resistant to current antibiotic therapy.
- A second ketolide, cethromycin (ABT 773), is in early development.

**Penicillins**

Among the oldest antibiotics still in use, some of the penicillins are not as effective as they used to be because specific bacteria have developed resistance to them. However, they remain active against a wide variety of bacteria, so they are still widely prescribed.

Figure A19

Therapy Class Drug Market Share Trend — Penicillins

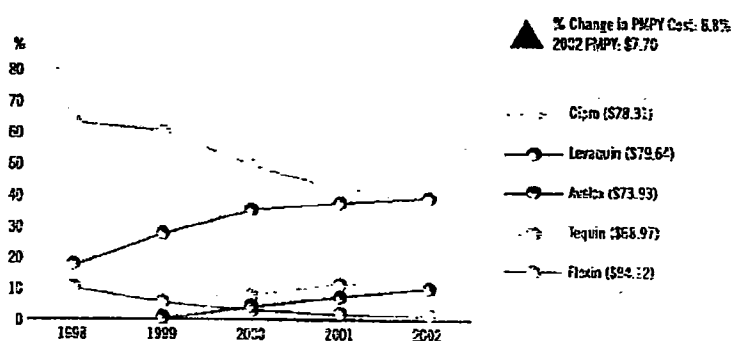


- In contrast to the double-digit growth experienced in 2001, PMPY ingredient costs for penicillins rose by a modest 2 percent in 2002. This marginal increase was fueled by a decline in the use of the Augmentin® product family and an increase in the use of less expensive generic amoxicillin.
- The generic fill rate in the class rose from 67.1 percent in 2001 to 71.8 percent in 2002.
- In the wake of federal court rulings that invalidated patents on Augmentin® (amoxicillin and clavulanate), generic versions of the 500mg and 875mg tablets began to be launched in the middle of 2002. They are being marketed under names such as Amoxyclav and Co-amoxiclav.
- Augmentin® XR, a new extended-release tablet form of Augmentin® has been approved for treating pneumonia and sinusitis in adults.

### Quinolones

A class of generally broad spectrum antibiotics, fluoroquinolones — often shortened to quinolones — was developed from an older class of antibiotics. The newer quinolones have a broad range of activity against some bacteria that do not respond to other types of antibiotics.

Figure A20  
Therapy Class Drug Market Share Trend — Quinolones



- PMPY cost for quinolones grew 8.8 percent, primarily driven by price increases.
- Cipro® (ciprofloxacin) continues to dominate this class, but it experienced a drop in market share from 42.0 percent in 2001 to 40.3 percent in 2002.
- A once-daily, extended-release dosage form of the quinolone antibiotic Cipro® (ciprofloxacin) was approved in late 2002. Cipro® XR is indicated once a day for 3 days to treat uncomplicated urinary tract infections. A generic equivalent for immediate-release Cipro® is expected on the U.S. market before the end of 2003.
- A second quinolone antibiotic, Lenvaquin® (levofloxacin) received a new indication for the treatment of hospital-acquired pneumonia.

#### Other Trends

- The re-submitted NDA for Factive® (gemifloxacin) is under consideration at the FDA after being found "not approvable" in 2000. The filing of an NDA for another new quinolone, garenoxacin, is on hold as the manufacturer reviews study results.

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## ANTIVIRALS

Viruses are responsible for some of the most common infections, as well as some of the most severe. On the more serious end of the spectrum of viral diseases is HIV/AIDS. Between 850,000 and 950,000 Americans have been infected with HIV, the virus that causes AIDS, according to 2000 figures from the National Institute of Allergy and Infectious Diseases.<sup>42</sup> Early and aggressive treatment of HIV means not only that people with AIDS are living longer but also that resistance to the drugs used to treat AIDS is increasing.

Hepatitis, inflammation of the liver, is caused by at least five different viruses:

- Hepatitis A (HAV) is most commonly spread by contaminated water or food. Affecting up to 35 percent of the U.S. population at some point in their lifetimes, HAV is usually mild with symptoms that resemble those from the flu. Vaccination can protect against HAV.<sup>43</sup>
- Hepatitis B (HBV) infects up to 320,000 Americans every year and about 5,000 deaths a year are attributed to chronic liver disease associated with it. While the great majority of patients recover, many who have had HBV carry the virus for life. Spread by contact with infected body fluids, HBV can be prevented by a vaccine. Natural immunity develops after a person has HBV.<sup>44</sup>
- Hepatitis C (HCV) currently infects approximately 41,000 Americans a year<sup>45</sup> with an estimated 4 million people in this country suffering from the chronic form of the disease.<sup>46</sup> Because HCV has few initial symptoms, up to half the people who have it do not know that they have the disease. Liver damage becomes apparent 10 years to 40 years after infection, making HCV the most frequent cause of liver transplantation in the United States. About 60 percent of HCV is due to intravenous drug use.<sup>47</sup> No vaccine is yet available to protect against HCV.
- Hepatitis D (HDV) and hepatitis E (HEV) are relatively uncommon in the United States, but they may be epidemic in other parts of the world.

<sup>42</sup> National Institute of Allergy and Infectious Diseases, National Institutes of Health, Fact sheet, HIV/AIDS statistics, August 2002. Available at: <http://www.niaid.nih.gov/factsheets/aidsstat.htm>. Accessed September 10, 2002.

<sup>43</sup> American Liver Foundation, Hepatitis A factsheet, Updated June 1, 1999. Available at: [http://64.227.163.135/cgi-bin/ds/articles.cgi?ds=articles&id=default&ID=1063&view\\_records=1](http://64.227.163.135/cgi-bin/ds/articles.cgi?ds=articles&id=default&ID=1063&view_records=1). Accessed September 10, 2002.

<sup>44</sup> American Liver Foundation, Hepatitis B factsheet, Updated July 23, 2002. Available at: [http://64.227.163.135/cgi-bin/ds/articles.cgi?ds=articles&id=default&ID=1062&view\\_records=1](http://64.227.163.135/cgi-bin/ds/articles.cgi?ds=articles&id=default&ID=1062&view_records=1). Accessed September 10, 2002.

<sup>45</sup> American Liver Foundation, Hepatitis C factsheet, Updated July 23, 2002. Available at: [http://64.227.163.135/cgi-bin/ds/articles.cgi?ds=articles&id=default&ID=1063&view\\_records=1](http://64.227.163.135/cgi-bin/ds/articles.cgi?ds=articles&id=default&ID=1063&view_records=1). Accessed September 10, 2002.

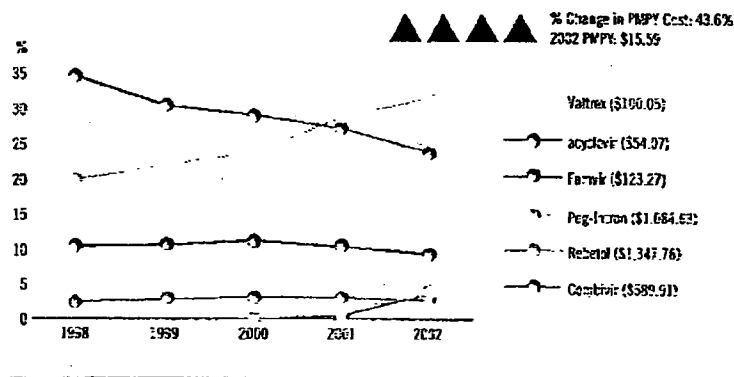
<sup>46</sup> National Center for Infectious Diseases, Centers for Disease Control and Prevention, National hepatitis C prevention strategy, Hepatitis C infection in the United States, last reviewed August 23, 2001. Available at: [http://www.cdc.gov/ncidod/diseases/hepatitis/c/plan/HCV\\_infection.htm](http://www.cdc.gov/ncidod/diseases/hepatitis/c/plan/HCV_infection.htm). Accessed September 9, 2002.

<sup>47</sup> National Center for Infectious Diseases, Centers for Disease Control and Prevention, National hepatitis C prevention strategy, Hepatitis C infection in the United States, last reviewed August 23, 2001. Available at: [http://www.cdc.gov/ncidod/diseases/hepatitis/c/plan/HCV\\_infection.htm](http://www.cdc.gov/ncidod/diseases/hepatitis/c/plan/HCV_infection.htm). Accessed September 9, 2002.

According to the CDC, up to 50 million Americans get influenza (flu) each year, mostly in the winter. Children are two to three times more likely as adults to have it, and people over the age of 65 may have more severe symptoms. Relatively minor for most of its victims, flu and its complications are responsible for more than 100,000 hospitalizations and more than 20,000 deaths annually.<sup>48</sup>

While usually mild, the common cold is possibly the most prevalent illness in the world. In 1996, the CDC estimated the total number of colds in the United States at 62 million, with nearly 85 percent affecting children under 18 years of age.<sup>49</sup> The common cold is caused by many different viruses, making both a cure and a preventive vaccine difficult to develop.

Figure A21  
Therapy Class Drug Market Share Trend — Antivirals



- PMPY ingredient costs for antivirals increased by 43.6 percent to \$15.59.
- While the utilization of these products grew by 7.6 percent, mostly from higher prevalence rates, the cost per prescription jumped by 33.5 percent.
- About two-thirds of this increase in the cost per prescription was attributable to mix changes. The market share for Rebetol<sup>®</sup>, with an average cost of \$1,348, grew from 0.4 percent to 3.7 percent. The market share for Peg-Intron<sup>™</sup> with an average cost of \$1,085, more than tripled to 3.7 percent.

48 National Institute of Allergy and Infectious Diseases, National Institutes of Health. Fact sheet. Fla. July 2001. Available at: <http://www.niaid.nih.gov/factsheets/flu.htm>. Accessed September 14, 2002.

49 National Center for Health Statistics, Centers for Disease Control and Prevention. Common cold. Last reviewed September 11, 2002. Available at: <http://www.cdc.gov/nchs/astats/colds.htm>. Accessed November 26, 2002.

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### **AIDS**

- A once-daily form of Zerit® (stavudine) was approved in January 2003.
- Orathecin™ (rubitecan) was granted Orphan approval for treating AIDS in children. It is an oral drug that is also in fast-track development for the treatment of pancreatic cancer.
- Fuzeon™ (enfuvirtide, formerly T-20) received FDA approval in March 2003 after undergoing a priority review. Fuzeon™ is the first in a new class of drugs known as fusion inhibitors that keep HIV from entering host cells. It requires a twice daily subcutaneous injection, and it must be used in combination with other types of anti-AIDS drugs. Because Fuzeon™ is difficult to manufacture, initial supplies are likely to be limited.
- T-1249 is a second fusion inhibitor, which is currently in Phase II development. However, it has received fast-track designation from the FDA. This drug attaches to a different part of the HIV molecule than Fuzeon™ does.
- Many possible vaccines for AIDS are in various stages of clinical and pre-clinical study. Most of them are therapeutic — meaning they are intended for people already infected with HIV. At least one preventive vaccine has reached Phase III trials. Preliminary results on its effectiveness, however, seem to show unexplained differences for certain ethnic groups.
- The NDA for atazanavir, a new protease inhibitor to be taken only once daily, was submitted to the FDA in September 2002.
- In November, the NDA for Coviracil® (emtricitabine), a once-a-day nucleoside reverse transcriptase inhibitor for HIV, was accepted by the FDA. Review of this drug is expected to take about a year.
- International phase III trials for a new type of protease inhibitor, tipranavir, are under way. As the first non-peptidic protease inhibitor (NPPi), tipranavir seems to have different resistance patterns from other antiviral drugs used to treat AIDS patients.

### **Hepatitis**

- The combination of Pegasys® (peginterferon alfa-2a) and Copegus™ (ribavirin) was approved in December 2002 for the treatment of adults with chronic hepatitis C.
- In December 2002, the FDA granted Orphan status to Civacir™ (Hepatitis C Immune Globulin [Human]) for the prevention of hepatitis C infection in liver transplant recipients.
- Hepsera™ (adefovir dipivoxil) was approved in 2002 for the treatment for chronic hepatitis B. Taken orally as a tablet, Hepsera™ inhibits an enzyme needed by HBV to replicate.
- Zadaxin® (thymosin alpha 1), a synthetic peptide, is continuing Phase III studies in the U.S. for hepatitis C and in Japan for hepatitis B. Zadaxin® is an immune system enhancer that is given by subcutaneous injection.

**Influenza**

- The maker of FluMist™ (cold-adapted live attenuated influenza vaccine, trivalent) has submitted additional data to the FDA. A first set of supplemental information had been submitted in January 2000, but even more clarification was requested.
- Research on an oral flu drug, peramivir, was halted in mid-2002 after results from Phase III testing showed no significant differences in the drug's effects compared to placebo.

**Colds**

- Following a "not approvable" finding by the FDA in mid-2002, research on a possible treatment for the common cold has been suspended. The FDA felt that the manufacturer had not provided enough documentation on possible interactions between the drug, Picovir™ (piconavir), and other drugs. Picovir™ is available on a limited basis for patients with severe or life-threatening diseases caused by picornaviruses.
- Another potential cold treatment, AG-7088, has finished Phase II trials. A protease inhibitor, AG 7088 is being tested as a nasal spray that is used several times a day.
- A second investigational nasal spray, INS37217, has also completed Phase II testing for rhinitis caused by colds and by allergies. Phase III trials began in late 2002.

**Other**

- A vaccine for human papillomavirus (HPV) is showing promise in Phase III trials. HPV is a precursor to cervical cancer.
- The HERPEVAC Trial for Women, a Phase III study, began in late 2002 for a vaccine that seems to prevent infection with Herpes simplex virus type 2 (HSV-2), which is a sexually-transmitted condition.

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## WOMEN'S HEALTH

Reproductive processes make women vulnerable to unique ailments, including endometriosis, menstrual disorders and pregnancy-related conditions such as gestational diabetes. In addition, women are more likely than men to have autoimmune diseases. For example:

- Systemic lupus erythematosus (SLE) is nine times more prevalent in women.<sup>50</sup>
- About two-thirds of the estimated 13 million Americans who suffer from urinary incontinence are women.<sup>51</sup>
- Fibromyalgia, a syndrome characterized by fatigue and chronic pain in the muscles and soft tissues surrounding joints, strikes nearly seven times as many women as men. An estimated 3.7 million American adults suffer from the condition.<sup>52</sup>

In June 2002, the FDA approved Bravelle® (urofollitropin for injection), another follicle-stimulating hormone to be used in combination with human chorionic gonadotropin in treating female infertility.

### Other Products

- In August 2002, the FDA issued an "approvable" letter for Prestara™ (prasterone), formerly known as Aslera® or GL701. Approval for the treatment of SLE is pending the results of additional testing requested by the FDA.
- The filing of an NDA is close for trospium in the treatment of overactive bladder, after a Phase III trial found decreases in both urgency and frequency of incontinence episodes in patients using the study drug as compared to those taking placebo.
- Phase III trials have begun in the United States, Britain and several countries in Africa and Asia to test a vaginal microbicide/contraceptive gel called SAVVY® (C31G). If approved, the product could prevent both conception and sexually-transmitted diseases such as chlamydia, gonorrhea and possibly even HIV. A similar product, PRO 2000, is in earlier stages of testing for its antimicrobial properties, only.
- Agile® (ethinyl estradiol and levonorgestrel) is a small contraceptive patch currently in Phase II / III studies.
- Preliminary results from a Phase II trial of milnacipran, the first drug to be studied specifically for fibromyalgia, show significant relief of pain and fatigue over placebo. Further analysis is expected before Phase III studies are initiated.

50. Jacobsen DL, Gange SJ, Rose NR, Graham RH. Epidemiology and estimated population burden of selected autoimmune diseases in the United States. *Clinical Immunology and Immunopathology*. 1997;84(2):223-243.

51. National Kidney and Urologic Diseases Information Clearinghouse. National Institute of Diabetes and Digestive and Kidney Diseases. National Institutes of Health. Urinary incontinence in women. May 2002. Available at: <http://www.niddk.nih.gov/health/urology/pubs/ui/women/uiwates.htm>. Accessed January 6, 2003.

52. National Institutes of Health. Arthritis prevalence rising as baby boomers grow older. Osteoarthritis is second only to chronic heart disease in work-site disability. [press release] May 5, 1998. Available at: <http://diis-cdb.org/wong/fmscreen.htm>. Accessed January 11, 2003.

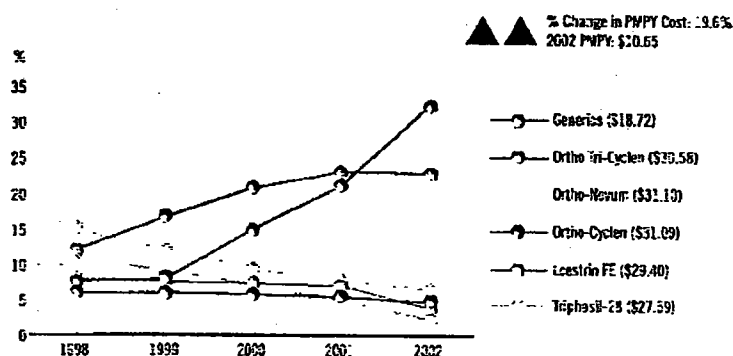


### Oral Contraceptives

Nearly 39 million American women between the ages of 15 and 44 use some form of contraception. About one-fourth choose oral contraceptives.<sup>55</sup>

Figure A22

Therapy Class Drug Market Share Trend — Oral Contraceptives



- PMPY costs for oral contraceptives grew by almost one-fifth to \$10.65 in 2002. The vast majority of this increase was due to higher utilization in the form of higher prevalence rates.
- Generics for the progesterone-only contraceptives NOR-QD<sup>®</sup> (norethindrone) and Ortho-Micronor<sup>®</sup> (norethindrone) were launched late in 2002 under the names Camila<sup>®</sup> and Errin<sup>®</sup>, respectively.
- In December 2002, the FDA gave approval for Tri-Sprintec<sup>®</sup> (ethinyl estradiol and norgestimate), a generic equivalent of Ortho Tri-Cyclen<sup>®</sup>. Earlier in the year, Portia<sup>®</sup> (ethinyl estradiol and levonorgestrel), a generic for Tri-Levlen<sup>®</sup>, was marketed. Also launched in mid-2002 was the previously approved product Enpresse<sup>®</sup> (ethinyl estradiol and levonorgestrel), the equivalent of Triphasil<sup>®</sup>.
- A generic for Mircette<sup>®</sup> (ethinyl estradiol and desogestrel) was approved in April 2002 under the name Kariva<sup>®</sup>.
- Necon<sup>®</sup> 7/7/7 (ethinyl estradiol and norethindrone), a generic version of Ortho-Novum<sup>®</sup> 7/7/7, was marketed in January 2003.
- A low-dose formulation of Ortho Tri-Cyclen<sup>®</sup> (ethinyl estradiol and norgestimate) was approved by the FDA in November 2002. It will be sold as Ortho Tri-Cyclen Lo<sup>®</sup>.

55 The Henry J. Kaiser Family Foundation. Contraceptive use and methods in the U.S. June 2002. Available at: [http://www.kff.org/contraception/26244/Contraception\\_Fact\\_Sheet\\_FINAL.pdf](http://www.kff.org/contraception/26244/Contraception_Fact_Sheet_FINAL.pdf). Accessed January 6, 2003.

- The contraceptive product Yasmin® (ethinyl estradiol and drospirenone) is increasingly popular because its unique progesterone component has a diuretic action that may promote temporary weight loss.

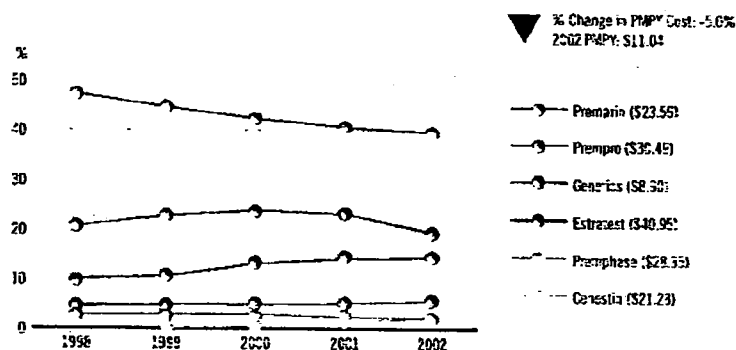
- The NDA for Seasonale® (ethinyl estradiol and levonorgestrel), an oral contraceptive intended to be used continuously for 84 consecutive days at a time, was accepted for review by the FDA in September 2002.

### Estrogens

The North American Menopause Society estimates that the average age of natural menopause is between 44 and 58 years. In 2000, approximately 40 million women in the United States were postmenopausal, a number expected to reach nearly 46 million by 2020.<sup>54</sup>

Figure A23

Therapy Class Drug Market Share Trend — Estrogens



- PMPY cost for estrogens dropped by 5 percent, due solely to a steep decline in use.
- Widespread publicity followed the early discontinuation of one part of the Women's Health Initiative (WHI) in the summer of 2002. An investigation of hormone replacement therapy's (HRT) role in protecting women against heart disease, the trial found that women using long-term combined estrogen and progesterone HRT had higher than expected rates of breast cancer, heart disease, stroke and blood clots. Results from the Heart and Estrogen/Progestin Replacement Follow-Up Study (HERS II) also showed that HRT did not prevent cardiac events for postmenopausal women with pre-existing heart disease. In January 2003, the FDA advised manufacturers of estrogens and combination estrogen/progesterone products to revise package labeling in ways that discourage the use of HRT when it is prescribed only to decrease the risks of cardiovascular disease.

<sup>54</sup> North American Menopause Society. About menopause. No Date Given. Available at: <http://www.menopause.org/aboutmenopause.pdf>. Accessed October 17, 2002.

- Even more startling results from the WHI were released in March 2003. Researchers concluded that combination HRT did not improve the quality of life for the majority of the women taking it. After 3 years of treatment, no significant clinical differences were noted between HRT and placebo in factors such as cognition, depression, general health or sexual satisfaction. Combination HRT did relieve hot flashes and sleep disruption for a subset of younger women, but the improvements were moderate and short-term. An editorial accompanying the study article recommends that all women consider alternatives to HRT and that women who choose to use HRT begin with low doses, re-evaluate treatment at frequent intervals and taper off the drugs as soon as possible.
- In large part because of these studies, the use of estrogens declined by 11.5 percent in 2002, resulting in a PMPY cost decrease of 5 percent in 2002.
- In January 2003, the FDA advised manufacturers of estrogens and combination estrogen/progesterone products to revise package labeling in ways that discourage the use of HRT when it is prescribed only to decrease the risks of cardiovascular diseases.
- A lower-dose formulation of Prempro™ (conjugated estrogens and medroxyprogesterone) was approved by the FDA in March 2003.
- The application for Estrasorb® (estradiol topical emulsion), a topical lotion containing estrogen, was resubmitted in September 2002. It had been withdrawn by the manufacturer in April 2002 after the FDA requested more information about the chemistry and manufacturing of the drug.

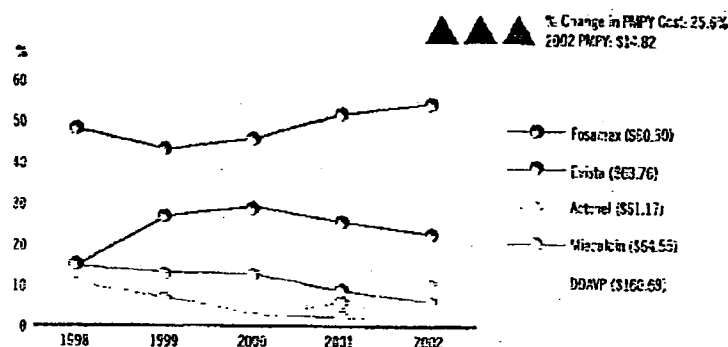
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### Miscellaneous Endocrines

Although the various types of miscellaneous endocrine drugs on the U.S. market treat conditions as diverse as growth deficiency and infertility, the biggest use in the class is for osteoporosis. The prevalence of osteoporosis after the age of 50 is estimated at 13 percent to 18 percent in women and 3 percent to 6 percent in men.<sup>55</sup>

Figure A24

Therapy Class Drug Market Share Trend — Miscellaneous Endocrines



- The controversy surrounding the use of estrogens resulted in large increases in the use of Fosamax<sup>®</sup>, Evista<sup>®</sup> and Actonel<sup>®</sup> in 2002, mirroring what happened in 2000 and 2001. Fueled by a 21.1 percent increase in utilization, principally from higher prevalence rates, 2002 PMPY costs for miscellaneous endocrines grew 25.6 percent to \$14.82.
- The combined market share of Fosamax<sup>®</sup>, Evista<sup>®</sup> and Actonel<sup>®</sup> rose from 83.3 percent in 2001 to 86.7 percent in 2002.
- Forteo<sup>®</sup> (teriparatide [rDNA origin] injection) was approved by the FDA in November 2002. A self-administered parathyroid hormone (PTH), it helps promote bone formation. Forteo<sup>®</sup> has been approved for both men and women at risk of fractures from osteoporosis.
- A generic for the bisphosphonate osteoporosis agent Fosamax<sup>®</sup> (alendronate), was tentatively approved in December 2002. Launch of the generic is pending the outcome of litigation over validity of the patent.
- FDA approval was granted in May 2002 for a once-weekly formulation of Actonel<sup>®</sup> (risedronate).
- The patent for Evista<sup>®</sup> (raloxifene), a selective estrogen receptor modulator (SERM) used to treat osteoporosis, has been challenged by a generic manufacturer.

55. Lindsay AC, Orwoll ES, Johnston CC Jr, and others. Prevalence of low femoral bone density in older U.S. adults from the NHANES III. *Journal of Bone Mineral Research*. 1997;12(11):1769-1771.

**Future Plans**

- A Phase III study, Treatment of Osteoporosis with PTH (TOP), is under way to test the effectiveness of Preos® (ALX 1-11) for osteoporosis. Earlier stages of testing are investigating the combination of Preos® with other drugs for osteoporosis. Like Forteo®, Preos® is a derivative of PTH that promotes the growth of new bone cells.
- Two "second-generation" SERMs are in Phase III trials — lasofoxifene for osteoporosis, and bazedoxifene for osteoporosis and hormone replacement.
- Long-term studies continue for tibolone, a synthetic steroid, in treating osteoporosis. The tentative brand names for tibolone are Xyvion® in the United States and Livial® in Europe.
- Positive results from a Phase III trial of a new oral bisphosphonate were presented in September 2002. In the Bonviva® Osteoporosis Trial in North America and Europe (BONE) study, patients taking Bonviva® (ibandronate) had fewer fractured vertebrae than patients taking placebo.
- An oral form of calcitonin, Oratomin®, is in early testing for osteoporosis.
- Although it is being contested as infringing on patent protection, the first application for a generic version of DDAVP® (desmopressin) has been filed with the FDA. Desmopressin is used for diabetes insipidus and nocturnal enuresis.

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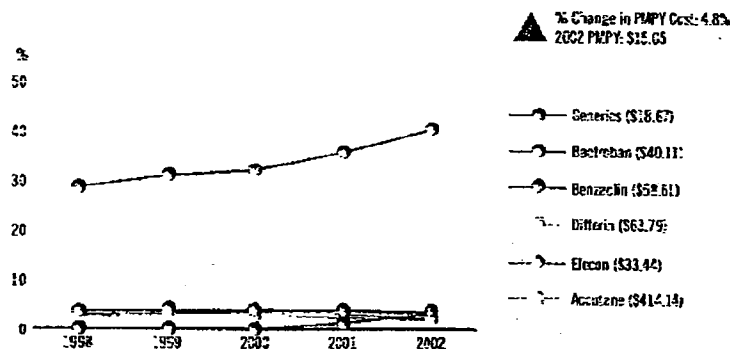
## DERMATOLOGICALS

According to the National Center for Health Statistics, about 35 million visits were made to dermatologists in 2000. In addition, over 13 million more visits to primary care doctors were related to rashes and other skin conditions.<sup>56</sup> Diseases of the skin affect every age group:

- Under the general category of dermatitis or eczema, skin rashes affect 10 percent to 15 percent of children under 18 years of age. While over 75 percent of children with dermatitis grow out of it by adolescence, a significant number continue to have skin problems into adulthood.<sup>57</sup>
- Around 5 million U.S. teens have acne considered bad enough to seek treatment.<sup>58</sup>
- Rosacea, a chronic but usually mild reddish rash on the face, affects about 14 million Americans — mainly women over the age of 30.<sup>59</sup>
- Over 5.5 million Americans — mostly adults — have psoriasis, a chronic skin condition characterized by itchy, painful scaling patches on the skin.<sup>60</sup>

Figure A25

Therapy Class Drug Market Share Trend — Dermatologicals



56 National Center for Health Statistics. NCHS fastats.—Dermatological conditions. 2000. Available at: <http://www.cdc.gov/nchs/fastats/skin.htm>. Accessed August 26, 2002.

57 Dermatology Channel. Atopic Dermatitis. No date given. Available at: <http://www.dermatologychannel.net/dermatitis/atopic.shtml>. Accessed September 14, 2002.

58 National Center for Health Statistics. NCHS fastats.—Dermatological conditions. 2000. Available at: <http://www.cdc.gov/nchs/fastats/skin.htm>. Accessed August 26, 2002.

59 National Institute of Arthritis and Musculoskeletal and Skin Diseases. Health Topics. Questions and answers about rosacea. Last Update June 2002. Available at: <http://www.niams.nih.gov/hi/topics/rosacea/rosacea.htm>. Accessed September 14, 2002.

60 National Institute of Arthritis and Musculoskeletal and Skin Diseases. Health Topics. Questions and answers about psoriasis. Last Update January 2002. Available at: <http://www.niams.nih.gov/hi/topics/psoriasis/psoriasis.htm>. Accessed September 14, 2002.

- Reversing the double-digit growth in PMPY costs seen over the last several years, the 2002 PMPY costs for dermatologicals rose by only 4.8 percent in 2002. An 8.8 percent increase in inflation overtook the 3.7 percent decline in utilization of these products.
- The generic fill rate in this class rose from 35.8 percent in 2001 to 40.4 percent in 2002.
- The FDA approved an application for Amevive® (alefacept) for the treatment of psoriasis in adults. Amevive® is an immunosuppressive agent injected either intravenously or intramuscularly once weekly in 12-week cycles.
- Tri-Luma® (fluocinolone, hydroquinone and tretinoin) is a new combination product approved in January 2002 for the treatment of facial hyperpigmentation.
- Finacea® (azelaic acid 15% gel) was approved by the FDA in January 2003 for the treatment of rosacea.
- A cream form of Zovirax® (acyclovir) was approved in January 2003 for the treatment of recurrent cold sores. The previous September saw the approval of a new indication in treating cold sores for Valtrex® (valacyclovir) tablets.
- In 2002, the FDA imposed more stringent restrictions on the dispensing of Accutane® (isotretinoin) for acne. Previously limited to a 30-day supply, prescriptions for Accutane® now cannot be phoned, faxed or e-mailed to pharmacies, they must be filled within one week of being written, and they must have a special sticker placed on them by the physician who wrote them.
- New generics for dermatology products include:
  - Amcinonide, the generic for Cyclocort®, a high-potency topical steroid for inflammatory skin conditions.
  - Betamethasone and clotrimazole, the generic for Lotrisone®, to treat fungal infections such as athlete's foot
  - Ketoconazole cream, the generic for Nizoral®, an antifungal
  - Isotretinoin capsules, the generic for the acne treatment, Accutane®

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#### ATTACHMENT A:

- A biological license application for the psoriasis medication Raptiva® (efalizumab; formerly known as Xelnelm®), was submitted to the FDA in December 2002. Raptiva® is a monoclonal antibody that inhibits inflammation in multiple ways. It is formulated to be taken by subcutaneous injection once a week. It is also in clinical trials for psoriatic and rheumatoid arthritis.
- Enbrel® (etanercept) and Remicade® (infliximab), two tumor necrosis factor alpha inhibitors already FDA-approved for other conditions, are showing effectiveness and few side effects when used for psoriasis. Both are in Phase III studies for psoriasis.
- Atrisor® (topical dapsone gel) is in the second planned Phase III clinical trial for acne. Both an antibiotic and an anti-inflammatory, oral dapsone is commonly used for preventing some opportunistic infections in immunocompromised patients.
- Botox® (botulinum toxin type A) continues to gain new uses. Already FDA-approved for some eye conditions, a painful neck condition and frown lines, Botox® is in various phases of investigation for conditions as diverse as migraine headaches, excessive sweating, anal fissures and post-stroke spasticity.
- Aldara® (imiquimod), which has been approved since 1997 for venereal warts, is now in clinical trials for actinic keratoses and basal cell carcinomas.
- Periostat® (doxycycline hyclate tablets) is in Phase III trials for rosacea and in earlier study for acne. It is already approved as a treatment for periodontitis in adults.
- PCL-016, the first member of a new class of drugs that bind to zinc-finger proteins, is in Phase II trials for acne. Zinc-finger proteins contain zinc ions and form parts of DNA chains. Each organism has unique zinc-finger protein structures.



## ANTIDIABETICS

According to a CDC estimate, 17 million Americans have diabetes, although approximately 6 million of those people may not realize they are diabetic. Millions more have a pre-diabetic condition called insulin resistance or impaired glucose tolerance (IGT). While diabetes has been diagnosed for only about 9 percent of the adult population over age 20 in the United States, it affects more than 20 percent of people over the age of 65.<sup>61</sup>

Only a small percentage of people with diabetes are diagnosed with type 1, which results from the inability to produce the natural hormone insulin. Type 2 diabetes, often associated with obesity, develops when the body cannot use insulin effectively.<sup>62</sup> Among U.S. adults, diagnosed diabetes increased nearly 50 percent between 1990 and 2000.<sup>63</sup>

The increased incidence of type 2 diabetes among children is even more dramatic. Until the 1990s, only around 0.5 percent of children who were newly diagnosed with diabetes had type 2. In the last 10 years, however, the incidence of new type 2 diabetes among children and adolescents has increased to between 8 percent and 45 percent, depending on geographic location and ethnic background.<sup>64</sup>

### Future Trends

Several products for the treatment of diabetes and its complications are in clinical development.

- AC2993 (synthetic exendin-4) is an injectable product in Phase III trials for the treatment of type 2 diabetes. In trials, it has controlled blood glucose levels but has not been associated as much with some of insulin's side effects — such as weight gain and hypoglycemia. Currently being tested as a twice-daily dosing, a once-monthly form is in earlier stages of testing.
- Subdexide (KRX-101) is on fast-track review from the FDA while its manufacturer conducts Phase III trials for diabetic nephropathy.
- DiaPep277 is a drug that may delay or halt the progression of type 1 diabetes. It is in Phase III testing in Europe and Israel. Phase II tests for its effectiveness against a diabetic condition called latent autoimmune diabetes are being conducted in several countries, including the United States.
- The overall cost of antidiabetics — both oral drugs and insulins — rose by 14.6 percent to \$25.66.

61 National Institute of Diabetes and Digestive and Kidney Diseases. National Institutes of Health. National diabetes statistics 2002. March 2002. Available at: <http://www.niddk.nih.gov/health/diabetes/press/consstats/consstats.htm>. Accessed January 10, 2003.

62 American Diabetes Association. Basic diabetes information. Available at: [http://www.diabetes.org/main/application/commmerce.fJSESSIOID\\_WLCS\\_DEFAULT=PPBLE2RpkwmodulRY2-SYwN5M4Yue2mqMP2Q1bXoVjaEPa4N9033G136584584238311197286997775017532?origin=-.jsp&event=fin4B](http://www.diabetes.org/main/application/commmerce.fJSESSIOID_WLCS_DEFAULT=PPBLE2RpkwmodulRY2-SYwN5M4Yue2mqMP2Q1bXoVjaEPa4N9033G136584584238311197286997775017532?origin=-.jsp&event=fin4B). Accessed January 30, 2003.

63 National Center for Chronic Disease Prevention and Health Promotion. Centers for Disease Control and Prevention. Diabetes: disabling, deadly, and on the rise. Last revised April 2, 2002. Available at: <http://www.cdc.gov/diabetes/pubs/stance.htm#rising>. Accessed September 13, 2002.

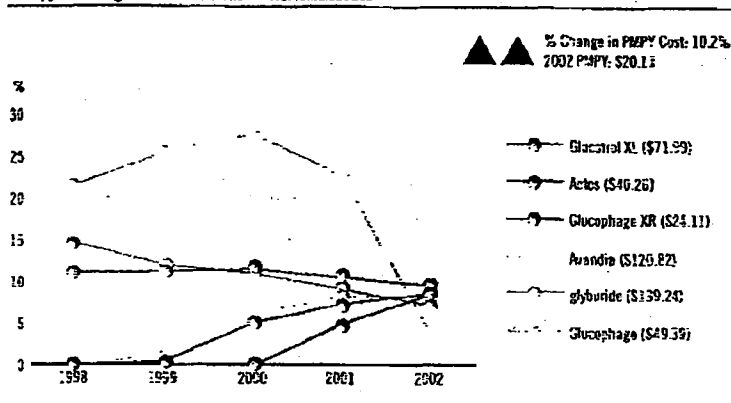
64 Kaufman FR. Type 2 diabetes mellitus in children and youth: a new epidemic. *Journal of Pediatric Endocrinology and Metabolism*. 2002;15(Suppl 2):737-744.

**Oral Antidiabetics**

By far the most common kind of diabetes is type 2. Affecting 90 percent to 95 percent of all people with diabetes,<sup>65</sup> type 2 often appears in middle-age. Obesity and lack of exercise are contributing factors, however, and type 2 is beginning to be seen more frequently among younger people — including children under 12. While type 1 diabetes usually requires insulin, type 2 frequently can be treated with oral medications — often in combination.

Figure A26

Therapy Class Drug Market Share Trend — Oral Antidiabetics



- PMPY 2002 costs of \$20.11 for oral antidiabetic drugs represent a 10.2 percent rise over 2001 levels. Most of this increase was due to higher utilization. The patent loss for Glucophage<sup>®</sup> and the subsequent introduction of its generic form metformin kept the cost per prescription relatively flat.
- Two oral combination products for type 2 diabetes were approved in 2002. Metaglip<sup>®</sup> combines metformin and glipizide; Avandamet<sup>®</sup> is a combination of rosiglitazone and metformin.
- Phase III trials of NN622 (ragaglitazar, DRF-2725) were discontinued in the summer of 2002 after bladder tumors were discovered in laboratory animals that had been treated with the drug during preclinical tests. Ragaglitazar would have been an oral dual-acting peroxisome proliferator-activated receptor alpha and gamma agonist insulin sensitizer.
- Development of another "glitazone" insulin sensitizer continues, however. Balaglitazone has advanced to Phase III trials.

65 National Institute of Diabetes and Digestive and Kidney Diseases, National Institutes of Health, National diabetes statistics 2002, March 2002. Available at: <http://www.niddk.nih.gov/health/diabetes/pubs/cmstats/dmstats.htm>. Accessed January 10, 2003.

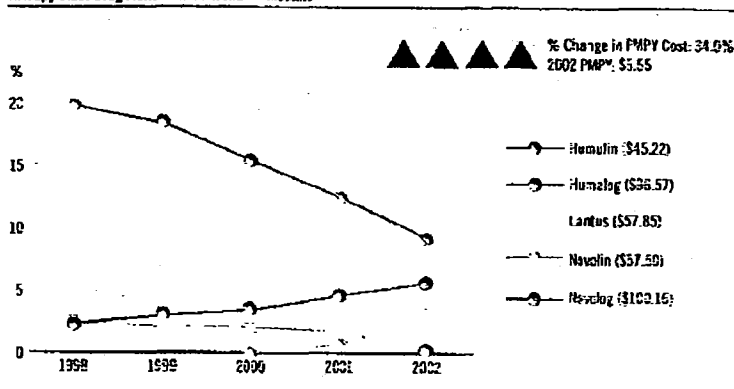
- Galida<sup>®</sup> (tesaglitazar, AZ242), the first investigational agent in a new class similar to "glitazones," is expected to enter Phase III testing this year.
- Recruitment of approximately 7,500 participants is completed for the Nateglinide and Valsartan in Impaired Glucose Tolerance Outcomes Research (NAVIGATOR) Trial. The 6-year international study will investigate the effects of Starlix<sup>®</sup> (nateglinide) and Diovan<sup>®</sup> (valsartan) both independently and in combination to prevent or delay the development of type 2 diabetes and cardiovascular disease. Starlix<sup>®</sup> is an FDA-approved amino acid derivative that enhances insulin secretion. Diovan<sup>®</sup> is an angiotensin-receptor blocker approved for treating hypertension.

### Insulins

Type 1 diabetes, formerly designated juvenile-onset diabetes, affects between 5 percent and 10 percent of people with diabetes.<sup>65</sup>

Figure A27

Therapy Class Drug Market Share Trend — Insulins



- PMPY costs for insulins rose by over one-third to \$5.55. Two-thirds of this increase was attributable to higher costs per prescription, primarily due to the rising market shares for higher-cost Humalog<sup>®</sup> and Lantus<sup>®</sup>, and corresponding declining shares for less expensive Humulin<sup>®</sup> products.
- In April, the FDA approved a new system for insulin delivery through insulin pumps. Designed to be more comfortable for users, the new system uses small patch-like strips that contain several tiny needles rather than one larger infusion needle as previous pumps do.

<sup>65</sup> National Institute of Diabetes and Digestive and Kidney Diseases, National Institutes of Health, National diabetes statistics 2002, March 2002. Available at: <http://www.niddk.nih.gov/health/diabetes/pubs/emstats/emstats.htm>. Accessed January 16, 2003.

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- An NDA was submitted to the FDA in December 2002 for insulin detemir (NN 304), a basal insulin.

- A fast-acting insulin, designated by the number HMR-1964, is in late Phase III development as monotherapy and in combination with the long-acting basal insulin Lantus® (insulin glargine).

- Research continues on alternate delivery systems for insulin. Among products in development are:

Exubera™ (inhaled insulin) is a rapid-acting, dry-powder form of insulin that completed a Phase III trial in early 2002. Although it appeared to control blood glucose comparably with injected insulin, Exubera™ also produced a slight decline in lung function among some of the study members — raising concerns that it may not be appropriate for people with respiratory problems.

Other insulins in development include Oraigen™ (Orafin® in Canada and Europe), which is meant to be administered buccally through an aerosol delivery system. Buccal agents are absorbed through the inner surface of the mouth. Oraigen™ is in Phase III and Phase II trials in various parts of the world.

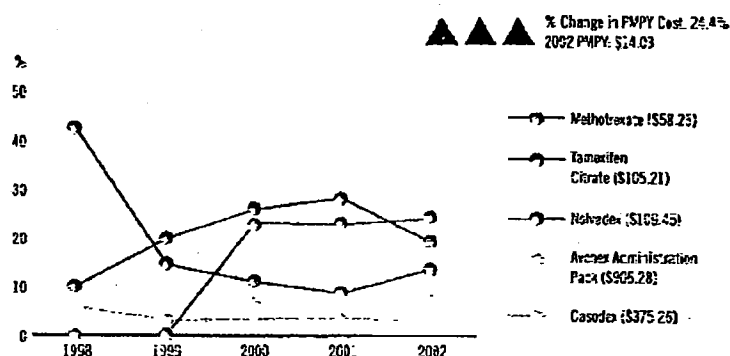
## ANTICANCER

Although various forms of cancer are more prevalent among children or young adults, 77 percent of cancer diagnoses in the United States are for people over the age of 54 years, according to the American Cancer Society.<sup>67</sup> Currently the second leading cause of death after heart disease, cancers account for approximately one-quarter of all deaths in the United States each year. More than 9 million Americans are living with active or remitted cancer, and nearly 2.3 million new cases of cancer — including about one million cases of skin cancers other than melanoma — are expected in the U.S. for 2003.

Approximately one-third of the 556,500 cancer deaths expected in this country during 2003 will be related to lifestyle factors such as nutrition, obesity, ultraviolet light exposure and lack of exercise. About 189,000 cancer deaths will be caused by the use of tobacco and/or alcohol.

Figure A29

Therapy Class Drug Market Share Trend — Anticancer



- 2002 PMPY costs for anticancer drugs grew by 24.4 percent to \$14.03. Over two-thirds of this increase was due to higher cost per prescription.

Currently, standard treatment for cancer usually includes surgery to remove tumors, then chemotherapy and/or radiation to kill any remaining cancer cells. As researchers focus on the ways that cancer cells differ from normal cells, they are discovering new drugs, new drug classes and new drug delivery methods. The majority of these new drugs are designed to work specifically against cancerous cells with less damage to normal cells. Many drugs are in development for multiple types of cancer, as well as for related or pre-cancerous conditions such as AIDS and hepatitis. For example, an investigational agent named Advexin<sup>®</sup> uses an adenoviral vector for the p53 tumor-suppressor gene. Injected directly into tumors, it is in Phase III trials for head and neck cancer, Phase II for breast, lung and head and neck cancers, and Phase I for bladder, brain, ovary and prostate cancers.

67 All statistics quoted in the Anticancer section are from American Cancer Society, Cancer Facts and Figures 2003. Posted 2/02. Available at: <http://www.cancer.org/downloads/STU/CAFF2003PWSecured.pdf>. Accessed February 19, 2003.

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PLEASE NOTE: Clinical trials of anticancer drugs usually test the new agent in combination with drugs that are already established as effective.

#### Brain Cancer

Brain cancers are not as common as other cancers — only about 18,000 cases of brain, spinal cord and other central nervous system malignancies are expected to be diagnosed in Americans this year.

- A fast-track designation was given to IL13-PE38, an investigational combination drug that attaches to interleukin 13 (IL13) receptors on the cell surfaces of malignant glioma, a highly aggressive type of brain tumor. A second component of the drug then destroys the cancer cells. Its manufacturer plans pivotal Phase III trials for 2003 and 2004. Already designated as an Orphan drug for glioma, IL13-PE38 is also in various phases of trials for other types of cancer.
- Also on fast-track for approval, a radiation-sensitizer designated as RSR 13 (efaproxiral) is undergoing Phase III testing for patients receiving radiation for metastatic brain tumors. In earlier trials, RSR 13 appeared to increase the effectiveness of radiation therapy for several types of cancer.
- A Phase III study is investigating the effectiveness of Xcytrin® (motexafin gadolinium) for patients with brain metastases from lung cancer. The first agent in a new class called texaphyrins, Xcytrin® and drugs like it are thought to keep cancer cells from repairing damage done by radiation or chemotherapy.
- The first immunotoxin — combining a normal blood component with an anticancer agent derived from diphtheria toxin — began Phase III trials in late 2002. The drug, currently called TransMID-107R, has both Orphan and fast-track designations in the United States.
- Also in Phase III is Cotara™, a tumor necrosis therapy (TNT) agent. Composed of a radiation source attached to a monoclonal antibody that is specific to dead tissue, Cotara™ has already attained Orphan status in the United States and the European Union, as well as having a fast-track designation in the United States.

#### Breast Cancer

About 211,000 new cases of invasive breast cancer and an additional 56,000 new cases of localized breast cancer are likely to be diagnosed among American women during 2003.

- Faslodex® (fulvestrant) was approved by the FDA in April 2002 for treating breast cancer. The first in a class of drugs that destroy estrogen receptors, Faslodex® is formulated for monthly intramuscular injections.
- In mid-February 2002, an AB-rated generic was marketed for Nolvadex® (tamoxifen). Several generic manufacturers made tamoxifen available almost immediately.

- Phase III trials involving more than 1,000 women continue for Theratope<sup>®</sup>, a potential therapeutic vaccine for breast cancer.

- A variation on paclitaxel, Xyotax<sup>™</sup> (polyglutamate paclitaxel) is in Phase III trials for metastatic breast cancer. The biodegradable polyglutamate carrier is a polymer that remains in normal blood vessels, but diffuses through the more permeable vessels that supply malignant tumors. As a result, more of the active drug accumulates in cancer tissue, and very little deposits in normal cells. Potentially, side effects are reduced. Xyotax<sup>™</sup> is also in Phase III trials for ovarian cancer and in earlier stages of testing for other types of cancer.

- In Phase III trials, another form of paclitaxel is also being tested for metastatic breast cancer. Currently designated as ABI-007, the nanoparticulate paclitaxel is tiny enough to be transported by red blood cells and then deposited as the blood enters tumor tissue. ABI-007 was given fast-track status in January 2003.

- Caelyx<sup>®</sup> (pegylated liposomal doxorubicin), a reformulation of a standard, first-line drug, is being studied for metastatic breast cancer. In Phase III studies it showed comparable efficacy to the originator drug but with a much lower incidence of serious cardiac side effects. Caelyx<sup>®</sup> is already approved in Europe and Canada for breast and ovarian cancers and Kaposi's sarcoma. A similar drug, Doxil<sup>®</sup> (doxorubicin liposome injection), has FDA approval for resistant ovarian cancer and Kaposi's sarcoma.

- Phase III trials began in late 2002 for atamestane, a drug that blocks an enzyme involved in estrogen production. In combination with a second drug that blocks estrogen receptors, atamestane is being tested for metastatic estrogen-dependent breast cancer.

- Modrenal<sup>™</sup> (trilostane) blocks estrogen binding in ways that are different from traditional breast cancer drugs to treat metastatic estrogen-dependent breast cancer. Modrenal<sup>™</sup> has been approved in the United Kingdom, and it is in clinical trials for breast cancer in the United States. The drug is also being investigated for ovarian, prostate and uterine cancers.

#### Colorectal Cancer

An estimated total of nearly 148,000 cancers of the colon and/or rectum will strike Americans during 2003. Over 90 percent of cases will occur in people aged 50 and older.

- In August 2002, Eloxatin<sup>™</sup> (oxaliplatin) was FDA-approved for treating colorectal cancer. To be used in combination with 5-fluorouracil and leucovorin, Eloxatin<sup>™</sup> will be given as an intravenous infusion once every 2 weeks.
- In February 2003, a limited access program was begun for patients with advanced colorectal cancer to receive Erbitux<sup>™</sup> (cetuximab, IMC 225), a monoclonal antibody that inhibits epidermal growth factor receptors. Erbitux<sup>™</sup> is in Phase II and Phase III clinical trials in the United States and Europe.

- A Phase III trial has enrolled 900 patients with metastatic colon cancer to study the effectiveness of Avastin™ (bevacizumab).

- Phase III colorectal cancer studies are scheduled to begin in 2003 for BAY 43-9006. An oral drug, BAY 43-9006 works by blocking a particular enzyme called raf kinase that is believed to be instrumental in tumor growth. The drug is in earlier phase trials for cancers of the breast, liver and pancreas.

- The therapeutic vaccine now known as ALVAC-CEA/B7.1 is in Phase II/III trials for colorectal cancer. Using ALVAC, a carrier derived from canary pox virus, the drug specifically seeks out a protein called carcinoembryonic antigen (CEA) that accumulates heavily on the surface of colon cancer cells.

- Phase III trials for a second therapeutic colorectal cancer vaccine are currently being conducted. The drug, TroVax®, uses modified vaccinia virus Ankara (MVA) as a vector. It attaches to ST4 antigens, which are common on the surfaces of malignant cells but not on normal cells. TroVax® is in earlier trials for a wide range of solid tumors.

- Phase II trials for both colorectal cancer and pancreatic cancer are underway for Aroplatin™, a drug that already has an Orphan indication for malignant mesothelioma. Aroplatin™ is a liposomal formulation of platinum.

#### Kidney Cancer

During 2003, renal cell carcinomas — cancers of the kidneys and the structures that surround them — will strike approximately 32,000 people in this country.

- In November 2002, the FDA gave an Orphan designation to Neovastat® (AE 941), for the treatment of renal cell carcinoma. Also in Phase III trials for lung cancer and Phase II trials for multiple myeloma, Neovastat® is an oral angiogenesis inhibitor derived from shark cartilage.

#### Leukemia

Nearly 31,000 new cases of leukemia potentially will be diagnosed in Americans during the year. About equally divided between acute and chronic forms of the condition, 90 percent or more of the cases will be in adults, and more men than women will be affected.

- In December 2002, Gleevec™ (imatinib), which inhibits an enzyme called tyrosine kinase, received a third indication for first-line treatment of adults with newly diagnosed chronic myeloid leukemia (CML) of the Philadelphia chromosome-positive (Ph+) type. Previously, it had been approved for chronic, accelerated or blast crisis CML, and for metastatic malignant gastrointestinal stromal tumors (GIST), a type of gastrointestinal cancer.

- Ceplene™ (histamine dihydrochloride) is believed to prevent the release of oxygen free radicals, natural chemicals that can suppress immune function. It is currently in Phase III clinical trials for the treatment of acute myelogenous leukemia and metastatic melanoma, as well as Phase II trials for advanced renal cell carcinoma.



- CEP-701 is a tyrosine kinase inhibitor currently being tested for adult patients with relapsed or unresponsive acute myeloid leukemia (AML) that is associated with a mutation in a specific gene, FLT3. It is in Phase II testing in the United States.

#### Liver Cancer

Relatively rare in the western world, liver cancer — also called hepatocellular carcinoma — is about four times more common in Asia than it is in Europe and North America. Its incidence is increasing in developed countries, however, as more people are infected with chronic hepatitis C. Liver cancers will develop in about 17,600 citizens of the United States this year.

- In August 2002, the FDA put on fast-track review the NDA for MTC-DOX, a drug previously designated as an Orphan product for primary liver cancer. The drug uses a magnetic targeted carrier (MTC) for the anticancer drug, doxorubicin. Powerful magnets positioned outside the body create magnetic fields which then draw the drug into specific locations.

#### Lung Cancer

The most common cause of cancer deaths among both men and women, lung cancer will be diagnosed in approximately 172,000 Americans in 2003. Lung cancers are generally identified by the size of the malignant cells that are involved. Non-small cell lung cancers (NSCLC) account for 75 percent to 85 percent of lung cancers in the nation.

- Taxotere® (docetaxel) has received FDA approval as first-line treatment of advanced or metastatic NSCLC in previously untreated patients. Taxotere® was already approved for NSCLC that resisted anticancer therapy and for metastatic breast cancer.
- A drug called tariquidar is on fast-track at the FDA for NSCLC. Belonging to a new class of drugs — P-glycoprotein (P-gp) inhibitors — tariquidar keeps P-gp from forcing anticancer drugs out of tumor cells. Phase III studies went on a planned and temporary hold in February 2002 while data on tariquidar's effectiveness and safety was analyzed.
- Iressa™ (gefitinib, ZD 1839), an oral epidermal growth factor receptor-tyrosine kinase inhibitor (EGFR-TKI), inhibits cell growth by blocking a key enzyme. In January 2003, the FDA extended fast-track review of Iressa™ for the treatment of NSCLC; an indication for which it is already approved in Japan.
- The maker of Tarceva™ (erlotinib, OSI-774) has enrolled approximately 1,200 patients with NSCLC in Phase III trials being conducted in several countries, including the United States. In combination with a number of anticancer drugs, Tarceva™ is also in earlier trials for colorectal, head, neck, ovarian and pancreatic malignancies.
- An antisense inhibitor, Affinitac™ (LY900003, ISIS 3521) is in international Phase II/III trials for NSCLC.

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- Aptosyn™ (exisulind), the first in a class called selective apoptotic antineoplastic drugs (SAANDs), is in various phases of trials for breast, colon, lung and prostate cancers. The most advanced is a Phase III study in combination with Taxotere™ (docetaxel) for NSCLC.
- Phase II trials for NSCLC are underway for Sarasar® (lonafarnib). Sarasar® is an FTI, a new class of drugs that inhibit an enzyme called farnesyl transferase. It is also being tested for other types of solid tumors and leukemia.
- Also in Phase II trials for NSCLC is angiostatin, an inhibitor of both angiogenesis and endothelial proliferation. Study participants receive intravenous infusions of other cancer agents, but they administer angiostatin themselves by two subcutaneous injections per day.
- Pivanex™, an analog of butyric acid, is also in Phase II trials for NSCLC. It inhibits histone deacetylase, an enzyme used by cancer cells to grow and spread.
- Resmycin™, a unique inhaled dose form of doxorubicin, began Phase II studies for NSCLC early in 2003. Using patented technology, it delivers the active drug directly into lung tissue.

#### Malignant Mesothelioma

A relatively rare but especially aggressive type of lung cancer, malignant mesothelioma develops over many years — mainly in older men who were exposed to asbestos on the work site. While only about 2,200 U.S. cases will be diagnosed in 2003, the average survival time after diagnosis is 6 months to 9 months.

- In July 2002, the FDA authorized an expanded access program for Alimta® (pemetrexed) to be used in combination with cisplatin for people with malignant pleural mesothelioma. Alimta® is in Phase III testing.
- An application for a fast-track designation was filed in October 2002 for another anti-mesothelioma agent, Onocase® (ranpirnase). If approved, Onocase® would be used in combination with doxorubicin.

#### Lymphoma

About 61,000 new cases of lymphomas — 85 percent or more of them the non-Hodgkin's type — are estimated to occur among Americans this year.

- Late in 2002, a second radiolabeled monoclonal antibody, Bexxar® (tositumomab, iodine I 131 tositumomab) was found "approvable" by an FDA committee. The manufacturer had presented additional information on the drug's effectiveness and safety. If approved, Bexxar® will be indicated for non-Hodgkin's lymphoma. The first agent of this type, Zevalin™ (ibritumomab tiuxetan), was FDA approved in February 2002.

- An NDA is expected to be filed by the end of 2003 for Onco TCS for the treatment of non-Hodgkin's lymphoma. Onco TCS consists of the anticancer drug vincristine that has been wrapped in a liposomal "transmembrane carrier system" (TCS). The resulting complex circulates relatively harmlessly in the blood, then deposits in tumor tissue. The drug is in Phase II for lymphoblastic leukemia and in various stages of development for several other cancer types.
- An antibody currently known as MDX-060 is in Phase II testing for several forms of lymphoma.

#### Melanoma

The most dangerous form of skin cancer, malignant melanoma is estimated to be diagnosed in over 54,000 Americans in 2003.

- In July 2002, Orphan status was given to Oncophage<sup>®</sup> (HSPPC-96), a therapeutic vaccine for metastatic melanoma. Oncophage<sup>®</sup> uses cells from each patient's excised melanoma tumors to create an individualized way to re-educate the patient's immune system. Cancer cells are targeted, but normal cells are left alone. The drug is also on fast-track review while Phase III trials continue for its effectiveness in both melanoma and kidney cancer.
- The FDA has also granted an Orphan designation for an angiogenesis inhibitor, endostatin, to be used in treating metastatic malignant melanoma.
- Another type of melanoma vaccine is derived from several standard melanoma cell lines, rather than from the individual tumors. At least two vaccines of this type — Canvaxin<sup>™</sup> and Melacine<sup>®</sup> are in U.S. Phase III trials.

#### Multiple Myeloma

Multiple myeloma, a cancer of the bone marrow, will strike around 15,000 U.S. citizens during the year.

- Velcade<sup>™</sup> (bortezomib) is an inhibitor of enzymes known as proteasomes, which help regulate cell function and growth. Temporary, periodic disruptions in proteasome function do not appear to affect normal cells drastically, but malignant cells divide more often, so they are more disrupted by proteasome fluctuations. In January 2003, an NDA was filed for Velcade<sup>™</sup> in multiple myeloma. Given both fast-track and Orphan status for that indication, Velcade<sup>™</sup> is also in various phases of clinical trials for a number of other cancers.
- Also granted an Orphan designation is a multiple myeloma vaccine called Mylovenge<sup>™</sup>, which is made from M protein, a tumor-produced antibody that circulates in the blood.
- In November, a version of thalidomide known by the investigational designation of ENMD 0995, achieved Orphan status for the treatment of multiple myeloma. Taken orally, ENMD 0995 inhibits angiogenesis and B-cell proliferation.

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- Another class of drugs similar in chemical structure to thalidomide is called immunomodulatory derivatives (IMiDs). In February, the first one, Revimid™ (CC-5013), gained a fast-track review designation for resistant or recurrent multiple myeloma. Revimid™ is being studied for several other cancers as well. A second IMiD, Actimid™ (CC-4047) is in Phase II trials for multiple myeloma and prostate cancer.

#### Ovarian Cancer

This year, just over 25,000 women in America will find out that they have cancer of the ovaries.

- Patent protection for Paraplatin® (carboplatin) is scheduled to expire in 2004. Indicated for ovarian cancer, Paraplatin® is widely used to treat a number of other cancers.
- A drug currently in Phase III trials for ovarian cancer and for NSCLC is called TLK286. It belongs to a group of "smart" anticancer agents that are not active until they come in contact with glutathione S-transferase P1-1 (GST P1-1), an enzyme highly secreted by cancer cells and only minimally secreted by normal cells. Once it becomes active, TLK286 promotes the death of the cells to which it adheres.
- Ovarex® (oregovomab) has both Orphan and fast-track designations from the FDA as it continues Phase III ovarian cancer trials in the United States and several other countries. A monoclonal antibody, OvaRex® is specific for CA 125 antigens that are present not only on ovarian cancer cells, but also in the blood of ovarian cancer patients.
- Phase II trials in treating ovarian cancer are ongoing for SGN-15, composed of a monoclonal antibody known as BR96 that contains doxorubicin. The drug is released after the drug-antibody composite attaches to malignant tumor cells that produce more BR96 antigens than normal cells do. SGN-15 is also in Phase II trials for NSCLC and prostate cancer.

#### Pancreatic Cancer

Because it has few early symptoms, cancer of the pancreas is usually advanced when it is diagnosed, resulting in a one-year survival rate of only about 20 percent. The incidence of new cases among Americans is anticipated to be 39,700 in 2003.

- In November 2002, Orathecin™ (rubitecan) was placed on a fast-track by the FDA. An inhibitor of the enzyme topoisomerase I, which plays a role in cell replication, Orathecin™ prevents cell division. Because cancer cells replicate much more rapidly than normal cells, they sustain more damage when cell division is disrupted.
- Also on fast-track for pancreatic cancer is Virulizin®, an immunotherapy drug that enhances the immune system in at least two ways — by inducing macrophage activity and by increasing tumor necrosis factor production. Virulizin® is in clinical trials for a number of other cancers, including Kaposi's sarcoma and melanoma.

- Avicine™ is a therapeutic vaccine in Phase III studies for pancreatic cancer. Using a unique mechanism of action, it elicits a specific immune response to human chorionic gonadotropin (hCG), a protein thought to be associated only with pregnancy and malignancy. Normally supporting the development of a fetus, hCG also appears to sustain tumor growth.
- GVAX® is a name for several therapeutic vaccines made from standard cancer cell lines maintained in laboratories. Cells from a single type of cancer are altered genetically to secrete a hormone, granulocyte-macrophage colony stimulating factor (GM-CSF), which induces immune response. In late Phase II trials is a GVAX® agent for pancreatic cancer. Other GVAX® targets include kidney, lung and prostate cancers and melanoma.
- Fast-track status was given in September 2002 to G17DT, an antigen that initiates immune response to cell growth factors involved in the growth and spread of cancer cells. G17DT is specific to gastrin 17 and gly-gastrin, which are not normally produced in the body. Already designated as an Orphen product in Australia and the European Union, G17DT is in Phase III clinical research for advanced pancreatic cancer, and in Phase II trials for both prostate and stomach cancers.

#### Prostate Cancer

Approximately 221,000 American men will be diagnosed with prostate cancer this year. More than 70 percent of the cases will be in men who are 65 years old or older.

- An NDA is expected to be resubmitted in early 2003 for Plenaxis™ (abarelix for injection). Plenaxis™ blocks the production of testosterone, which promotes the growth of prostate cancer.
- Phase III testing of atrasentan (ABT-627), a selective endothelin-A receptor antagonist (SERA), continues for men with localized prostate cancer. Atrasentan is also being investigated for multiple other solid tumor types.
- Panzem™ (2-Methoxyestradiol or 2ME2), an oral drug, is believed to destroy both cancer cells and the blood vessels that supply them through activation of a receptor (Death Receptor 5 or DR5) specific to malignant cells. It is most advanced in Phase II studies for prostate cancer, but it is also being tested for breast cancer and myeloma.

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DRUG TREND  
2002 Report

## Medicaid Prescription Drugs

### History

In 1965, amendments to the Social Security Act (SSA) established Medicare and Medicaid. Both programs were designed to provide publicly-funded healthcare for low-income Americans across the nation. Initially, Medicaid covered limited healthcare services for certain children and the relatives taking care of them, as well as for elderly, blind and disabled people unable to afford health insurance. Program expansions have extended benefits for eligible recipients to include prenatal and infant care; preventive, diagnostic and treatment services for children; medical care for the working poor and a wide range of other services.

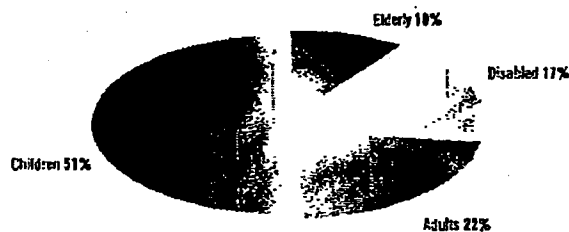
### Enrollment

About one American in seven uses Medicaid at some time in a given year.<sup>1</sup> During FY 2002, Medicaid served nearly 48 million recipients (approximately 24 million children, 13 million elderly or disabled people and 11 million non-elderly, non-disabled adults).<sup>2</sup> (See Figure B1). While children make up the largest group of Medicaid recipients, they account for less than 20 percent of Medicaid spending.<sup>3</sup> Approximately two-thirds of Medicaid money covers care for about one-third of participants who are elderly or disabled.<sup>4</sup> By 1998, for instance, Medicaid was responsible for medical costs incurred by as many as 90 percent of American children living with AIDS and more than half of all U.S. AIDS victims.<sup>5</sup> Because of the large percentage of high healthcare utilizers among Medicaid recipients, people on Medicaid use services more intensely than the general population.<sup>6</sup>

- 1 Kaiser Commission on Medicaid and the Uninsured. State budgets under stress: how are states planning to reduce the growth in Medicaid costs? July 30, 2002. Available at: <http://www.kff.org/content/2002/20020730/20020730.pdf>. Accessed October 3, 2002.
- 2 Smith V, Ellis E, Gifford K, Ramesh R, Wachino V. Medicaid spending growth: results from a 2002 survey. Kaiser Commission on Medicaid and the Uninsured. September 2002. Available at: <http://www.kff.org/content/2002/20020904/20020904.pdf>. Accessed October 3, 2002.
- 3 DePaola N-A. A profile of Medicaid. Chartbook 2000. Health Care Financing Administration, U.S. Department of Health and Human Services. September 2000. Available at: <http://cms.hhs.gov/statistics/2/chartb1a.pdf>. Accessed November 12, 2002.
- 4 Smith V, Ellis E, Gifford K, Ramesh R, Wachino V. Medicaid spending growth: results from a 2002 survey. Kaiser Commission on Medicaid and the Uninsured. September 2002. Available at: <http://www.kff.org/content/2002/20020904/20020904.pdf>. Accessed October 3, 2002.
- 5 Fenz G. State Coverage Initiatives Issue Brief. State health care spending: a systems perspective. 2002;3(1). Available at: <http://www.statecoverage.net/pdf/issuebrief1502.pdf>. Accessed October 16, 2002.
- 6 Centers for Medicare and Medicaid Services. U.S. Department of Health and Human Services. Fact Sheet. Medicaid and acquired immune deficiency syndrome (AIDS) and human immunodeficiency virus (HIV) infection. Last updated April 18, 2002. Available at: <http://cms.hhs.gov/hiv/aids/fact.asp>. Accessed November 12, 2002.
- 7 Smith V, Ellis E, Gifford K, Ramesh R, Wachino V. Medicaid spending growth: results from a 2002 survey. Kaiser Commission on Medicaid and the Uninsured. September 2002. Available at: <http://www.kff.org/content/2002/20020904/20020904.pdf>. Accessed October 3, 2002.



Figure B1  
Medicaid Enrollment Sectors 2001



Adapted from: Kaiser Commission on Medicaid and the Uninsured. State budgets under stress: how are states planning to reduce the growth in Medicaid costs? July 30, 2002. Available at: <http://www.kff.org/medicaid/2802/28020733/28020733.pdf>. Accessed October 3, 2002.

#### Enrollment Volatility

The Medicaid population is highly volatile, with some enrollees changing status frequently — usually when income changes. According to the 2000 HCFA Chartbook, the average length of time that any person is eligible annually is 9 months.<sup>6</sup> Income eligibility for most optional and mandatory eligibility groups is tied to the federal poverty limit (FPL), which was set for FY 2002 at \$8,860 for an individual and \$18,100 for a family of four in the contiguous 48 states or the District of Columbia.<sup>7</sup> Alaska, Hawaii and the territories use slightly different thresholds to administer their programs.

In one notable exception to the income eligibility rules, states may choose to extend Medicaid coverage to low-income, uninsured women under the age of 65 who need treatment for breast or cervical cancer, as discovered through the Centers for Disease Control and Prevention's National Breast and Cervical Cancer Early Detection program. Most states participating in the program waive income and asset limits for women who qualify under the Federal Breast and Cervical Cancer Prevention and Treatment Act of 2000.

6 DeParle H-A. A profile of Medicaid. Chartbook 2000. Health Care Financing Administration. U.S. Department of Health and Human Services, September 2000. Available at: <http://cms.hhs.gov/statistics/2/chartbk.pdf>. Accessed November 12, 2002.  
7 67 Fed. Reg. 6931 (February 14, 2002) Annual Update of the HHS Poverty Guidelines. From the Federal Register Online via GAO Access. Available at: <http://webgate.access.gpo.gov/cgi-bin/haigate.cgi?WASdocID=38012827632+0+0+0&WASAction=retrieve>. Accessed November 15, 2002.

**Eligibility Requirements**

To comply with federal requirements, states/territories must extend Medicaid to:

- Families who receive Temporary Assistance for Needy Families (TANF) cash assistance
- Children under 6 with family income under 133 percent of the FPL
- Pregnant women and children under age 1 with family income under 133 percent of the FPL
- People receiving SSI (unless the state is a 209(b) state)
- Some Medicare recipients
- Children under age 18 in families with incomes below 100 percent of the FPL<sup>10</sup>

It should be noted that for the mandatory category TANF, the state establishes a percent of the federal poverty level. For example, in one state the eligibility income level may be set at 40 percent and in another at 77 percent of the federal level.

The administering jurisdiction may also choose to cover other populations that may include:

- Low-income parents (beyond the mandatory TANF group)
- Medically needy individuals (those with high medical bills who would be eligible if their incomes/assets were low enough)<sup>11</sup>
- Some working disabled people who would qualify for Supplemental Security Income (SSI) if they did not have work income
- Individuals residing in nursing facilities with incomes between 100 percent and 300 percent of SSI
- Individuals living in community settings but who would be eligible if they were institutionalized

Medicaid enrollment is on the rise. The recent recession means more unemployment and, therefore, more people eligible for Medicaid, as well as less state revenues to fund the growing Medicaid population. One estimate is that Medicaid will gain approximately 1.6 million new enrollees for each percentage point that unemployment rises.<sup>12</sup> In addition, an aging population means more low-income elderly participants will enter the system. For FY 2003, general enrollment is expected to increase about 9 percent across the states.<sup>13</sup>

The Administration's 2004 federal budget proposed significant changes to the Medicaid structure. Under the proposed new rules, states would be allowed to revise their Medicaid programs for optional recipients without needing to obtain federal waivers. Approximately one-third of Medicaid

10 Centers for Medicare and Medicaid Services, U.S. Department of Health and Human Services, Medicaid: a brief summary, last updated July 30, 2002. Available at: <http://cms.hhs.gov/publications/overview-medicare-medicaid/default.asp>. Accessed September 25, 2002.

11 Coughlin TA, Zuckerman S. States' use of Medicaid maximization strategies to top federal revenues: program implications and consequences. Urban Institute, June 2002. Available at: [http://www.urban.org/UploadedPDF/313525\\_DFO203.pdf](http://www.urban.org/UploadedPDF/313525_DFO203.pdf). Accessed October 29, 2002.

12 Smith V, Ellis E, Gifford K, Ramesh R, Wachino V. Medicaid spending growth: results from a 2002 survey. Kaiser Commission on Medicaid and the Uninsured, September 2002. Available at: <http://www.kff.org/content/2002/4364/4364.pdf>. Accessed October 3, 2002.

13 Smith V, Ellis E, Gifford K, Ramesh R, Wachino V. Medicaid spending growth: a 50-state update for fiscal year 2003. Kaiser Commission on Medicaid and the Uninsured, January 2003. Available at: <http://www.kff.org/content/2003/20030113/2003.pdf>. Accessed January 14, 2003.

recipients receive benefits under programs states choose to offer. Benefits could be extended — or denied — to specific groups or individuals without affecting the entire population.<sup>14</sup>

Greater emphasis would be placed on home and community care settings to prevent or delay institutionalizing Medicaid recipients. In addition, fixed amounts of money rather than matching funds would be given to the states for financing both Medicaid and the State Children's Health Insurance Program (SCHIP). Established in 1997, SCHIP is funded by federally matched block grants that allow states to provide healthcare coverage for children whose family incomes are below 200 percent of the FPL and who do not have private health insurance or Medicaid eligibility. States can use federal funds to initiate child-health programs, expand Medicaid or both. In FY 2002, SCHIP covered about 5.3 million children under the age of 18.<sup>15</sup> States that participate voluntarily in the new system would receive one federal dispersal for acute care and a separate allowance for long-term and community care. Similar to the current SCHIP plan, states could then transfer money between the funds as needed. States that do not opt for the new plan would still operate their Medicaid and SCHIP programs under current rules.<sup>16</sup>

### Services

Broad general guidelines for Medicaid programs are determined by the Centers for Medicare & Medicaid Services (CMS, formerly the Health Care Financing Administration, or HCFA) of the U.S. Department of Health and Human Services. Each state or territory, however, establishes its own recipient eligibility criteria, service offerings and provider payment scales.<sup>17</sup> The result essentially amounts to 56 different plans with wide variations in the range of services offered.

To qualify for federal funding, each jurisdiction must provide specific basic health services, such as:

- Inpatient and outpatient hospital care
- Laboratory and radiology testing
- Physician services
- Prenatal care
- Family planning
- Vaccinations and periodic health examinations for recipients under 21 years of age (referred to as EPSDT)<sup>18</sup>

<sup>14</sup> Leuka E. Advocates for poor criticize Bush's Medicaid proposal. *The Wall Street Journal*, February 3, 2003.

<sup>15</sup> Centers for Medicare and Medicaid Services. U.S. Department of Health and Human Services. Fiscal year 2002 number of children ever enrolled in SCHIP — preliminary data summary. January 30, 2003. Available at: <http://cms.gov/schip/schip02.pdf>. Accessed February 17, 2003.

<sup>16</sup> Bush administration will propose private improvements in states' health coverage for low-income Americans (press release). U.S. Department of Health and Human Services. January 31, 2003. Available at: <http://hhs.gov/news/press/2003pres/20030131a.html>. Accessed February 11, 2003.

<sup>17</sup> Centers for Medicare and Medicaid Services. U.S. Department of Health and Human Services. Medicaid: a brief summary. Last updated July 30, 2002. Available at: <http://cms.hhs.gov/publications/overview-medicare-medicare/default.asp>. Accessed September 25, 2002.

<sup>18</sup> Centers for Medicare and Medicaid Services. U.S. Department of Health and Human Services. Medicaid: a brief summary. Last updated July 30, 2002. Available at: <http://cms.hhs.gov/publications/overview-medicare-medicare/default.asp>. Accessed September 25, 2002.

States and territories may also choose to cover more than 30 additional services including:

- Dental care
- Eyeglasses and eye examinations
- Hospice
- Physical therapy
- Prescription drugs
- Prostheses

Any of the Medicaid-offered services — required or optional — can be limited in type, length or extent; but states must assure that services are long enough and broad enough to produce reasonable results. Services must be the same for all Medicaid recipients in the state, unless a waiver designating specific locations as demonstration sites is in effect.<sup>19</sup> In addition, services may not be restricted in ways that could discriminate unfairly against persons with certain conditions or diagnoses.<sup>20</sup>

#### Waivers

CMS reviews and approves state proposals for Medicaid service delivery. Major changes may require a waiver, which is a suspension of federal requirements that allows a Medicaid agency to try new ways of providing services. Waivers typically last for a defined period of time, but they can be renewed. Programs authorized under waivers must not be more expensive to the federal government than the services they replace, and they must represent substantial innovations to existing services. Waivers are authorized under two sections of the SSA:

1. A section 1115 "Research and Demonstration" waiver allows states to test pilot programs that may "promote the objectives of the Medicaid program"<sup>21</sup> and possibly benefit other Medicaid sponsors.
2. A section 1915 "Program" waiver gives Medicaid administrators more flexibility in expanding services for Medicaid recipients — including requiring Medicaid recipients to enroll in managed care programs or developing alternative community-based care systems.

19. Schlossberg C, Jersin S. Fact sheet: prescription drug coverage under Medicaid. National Health Law Program. July 1999. Available at: <http://www.healthlaw.org/outlet/15999608MedicaidDrugs.html>. Accessed November 15, 2002.

20. Centers for Medicare and Medicaid Services. U.S. Department of Health and Human Services. Medicaid: a brief summary. Last Updated July 30, 2002. Available at: <http://cms.hhs.gov/publications/overview-medicare-medicare/default4.asp>. Accessed September 25, 2002.

21. Health Care Financing Administration. U.S. Department of Health and Human Services. Medicaid and SCHIP waivers: promoting state flexibility and innovation. May 9, 2001. Available at: <http://www.hhs.gov/news/press/2001pres/0115medicaid.html>. Accessed November 27, 2002.

Appendix B	Appendix A	Actions	Specialty Incentives	Cost Forecast	Trends in Expenditures	Introduction	Preface	Table of Contents
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### **Medicaid Managed Care**

Arizona was the last state to implement a Medicaid program in October 1982. Unlike other states, which offered mainly fee-for-service (FFS) Medicaid plans, Arizona obtained federal permission to establish the first statewide all-managed care system, the Arizona Health Cost Containment System, (AHCCS).<sup>22</sup> Twenty years later, nearly 60 percent of Medicaid enrollees across the country were in managed care plans<sup>23</sup> (see Figure B2).

After a period of managed care growth, however, health plans began leaving the Medicaid market in the late 1990s as their profits declined. Especially hard hit were large plans with relatively high percentages of non-Medicaid enrollees. Health plans operating on small margins per individual need a big and diverse pool of participants, but welfare reform reduced Medicaid enrollments. At the same time, some states drastically cut the rates paid to the plans.

Currently operating in the District of Columbia, in some of the territories and in every state except Alaska and Wyoming, Medicaid managed care programs range from nearly "universal" care to very limited programs for specific populations. Most states and territories use mixed models that combine two basic types of features:

1. In the HMO or prepaid health plan model, providers receive a capitated fixed monthly fee for each recipient. The provider assumes financial risk for services that exceed the payment. In 2001, approximately 70 percent of Medicaid managed-care enrollees were in a prepaid plan.<sup>24</sup>
2. The primary care case management (PCCM) model uses a primary physician, physician assistant or nurse practitioner "gatekeeper" to coordinate care for individual Medicaid recipients. Providers assume no financial risk, receiving instead a set monthly case management fee for each recipient.<sup>25</sup>

A recent report from the Center for Health Care Strategies used representative prescription cost and utilization data to compare FFS and managed care Medicaid plans. While the study found that prescription prices paid to pharmacies before rebates were about the same for both types of plan, managed Medicaid was able to achieve a 10 percent to 15 percent lower overall cost for

22 Arizona Health Care Cost Containment System. 2001. AHCCCS Overview: Chapter 1. Beginnings and future of AHCCCS. 2001. Available at: [http://www.ahcccs.state.az.us/Publications/Overview/2001/Chapter1/Chapter1\\_2001.asp](http://www.ahcccs.state.az.us/Publications/Overview/2001/Chapter1/Chapter1_2001.asp). Accessed November 26, 2002.

23 Centers for Medicare and Medicaid Services. U.S. Department of Health and Human Services. National summary of Medicaid managed care programs and enrollment. June 30, 2002. No Data Given. Available at: <http://cms.hhs.gov/medicaid/managedcare/nrcs02.pdf>. Accessed December 10, 2002.

24 Centers for Medicare and Medicaid Services. U.S. Department of Health and Human Services. Medicaid drug rebate program. Last updated May 22, 2002. Available at: <http://cms.hhs.gov/medicaid/drugs/drugimgg.asp>. Accessed November 26, 2002.

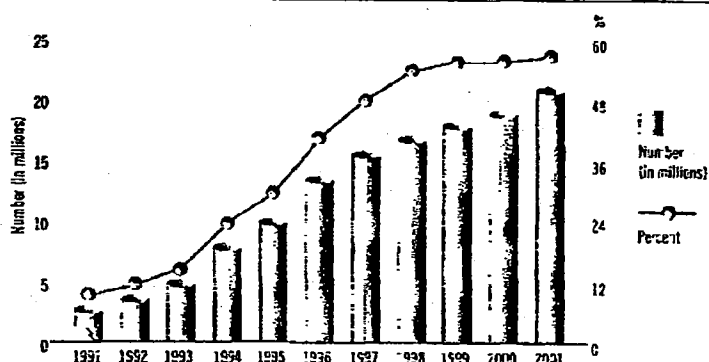
25 Kaiser Commission on Medicaid and the Uninsured. Medicaid and Managed Care. December 2001. Available at: <http://www.kff.org/content/2001/206803.pdf>. Accessed September 23, 2002.

26 Centers for Medicare and Medicaid Services. U.S. Department of Health and Human Services. Medicaid drug rebate program. Last updated May 22, 2002. Available at: <http://cms.hhs.gov/medicaid/drugs/drugimgg.asp>. Accessed November 26, 2002.

27 Kaiser Commission on Medicaid and the Uninsured. Medicaid and Managed Care. December 2001. Available at: <http://www.kff.org/content/2001/206803.pdf>. Accessed September 23, 2002.

pharmacy services. In general, FFS plans received larger average rebates. Managed care plans, however, more than made up the difference by paying much lower dispensing fees, using stricter formularies and increasing generic utilization. Although selection bias and different requirements for retrospective coverage may have influenced the finding, managed pharmacy plans also appeared to result in significantly fewer prescriptions dispensed PMPM, as well.<sup>24</sup>

Figure B2  
Growth of Enrollment in Medicaid Managed Care Programs by Percent of Recipients 1991-2001



Adapted from: Centers for Medicare and Medicaid Services. National Summary of Medicaid Managed Care Programs and Enrollment, Managed Care Trends, June 30, 1996. Available at: <http://www.cms.hhs.gov/medicaid/managedcare/trends1.pdf> and National Summary of Medicaid Managed Care Programs and Enrollment, June 30, 2001. Available at: <http://www.cms.hhs.gov/medicaid/managedcare/trends01.asp>. Both accessed February 18, 2003.

### Prescription Drug Coverage and Pricing

Even though a drug benefit is optional under Medicaid, all states and territories provide at least some outpatient prescription drug coverage.<sup>25</sup> Averaging about 10 percent of the total Medicaid spending in each state,<sup>26</sup> prescription drugs cost Medicaid programs nearly \$12 billion in FY 1998. In comparison, Medicaid expenditures in FY 1998 included \$44 billion for long-term institutional care, almost \$29 billion for hospitalizations, close to \$28 billion for health insurance, about \$12 billion for community-based long-term care, nearly \$7 billion for physician services and approximately \$6 billion for ancillary medical services such as laboratory tests and X-rays.<sup>27</sup>

28. Beron, M., Menges, J., Cheng, A. Comparison of Medicaid pharmacy costs and usage between the fee-for-service and capitated setting. Center for Health Management Strategies, January 2003. Available at: <http://www.chms.org/resource/cd/C-DCSParmacy.pdf>. Accessed February 21, 2003.

25. Yackler, H.G. Outpatient prescription drugs: requisition and reimbursement policies under selected federal programs. August 9, 1995. Available at: <http://medpolicy.com/studies/crs-outpatient/crnying-0899.pdf>. Accessed November 25, 2002.

30. Smith, Y., Ellis, E., Gifford, K., Ramresh, R., Wachira, V. Medicaid spending growth: results from a 2002 survey. Kaiser Commission on Medicaid and the Uninsured, September 2002. Available at: <http://www.kff.org/content/2002/4664/4064.pdf>. Accessed October 3, 2002.

31. DeParle, M.A. A profile of Medicaid. Chartbook 2000. Health Care Financing Administration, U.S. Department of Health and Human Services, September 2000. Available at: <http://cms.hhs.gov/statistics/2000/chartbk.pdf>. Accessed November 12, 2002.



amount of drugs dispensed.<sup>36</sup> The Medicaid agencies, in turn, reimburse participating pharmacies.<sup>37</sup> Partly in response to legal challenges on behalf of pharmaceutical manufacturers, the CMS formally restated in September 2002 that individual Medicaid programs can negotiate their own supplemental rebates directly with manufacturers and can establish a preferred drug list as a mechanism for obtaining additional rebates from manufacturers. Drugs not on that list require prior authorization.<sup>38</sup> Rebate amounts reflect a percent of the state's net drug spend, and depend on both the volume of specific drugs that are used and the state's arrangements with individual drug manufacturers. In 1999, a sample of state pharmaceutical programs reported receiving a wide range of rebate dollars, with the most common amounts being in the 10 percent to 20 percent range.<sup>39</sup>

#### Other Volume-Based Price Discounts

To acquire even better volume pricing, some individual states combine their drug purchasing for several departments, such as employees' health plans, health departments, prison systems and Medicaid. Additionally, states are beginning to join purchasing groups so they can attain more efficiency in the acquisition of pharmaceuticals.

#### Expenditures

In 1966, the first full year of its operation, Medicaid spending amounted to under \$1 billion on behalf of about 4 million recipients.<sup>40</sup> For FY 2002 (July 1, 2001 through June 30, 2002), the estimated total Medicaid expenditure was \$248 billion, with about \$142 billion from federal funding and the rest from the state and local governments.<sup>41</sup> Original enrollment has multiplied nearly 12-fold, and the average annual outlay per participant has increased from about \$200 to over \$6,000.<sup>42</sup> In 2002, Medicaid spending increased 13.4 percent overall, after an 11 percent rise in 2001.<sup>43</sup> For FY 2003 total Medicaid spending is expected to increase by about 9 percent on average.<sup>44</sup>

36. Tacker HG. Outpatient prescription drugs: acquisition and reimbursement policies under selected federal programs. August 9, 1999. Available at: <http://rxpolicy.com/studies/cro-cousetentiairying-0999.pdf>. Accessed November 26, 2002.
37. Hansen J. United States prescription drug pricing and reimbursement policies. The European Agency for the Evaluation of Medicinal Products. No Date Given. Available at: <http://pharmecce.europa.org/53/g1/docs/usa/usa.pdf>. Accessed November 25, 2002.
38. Smith DG. Letter to State Medicaid Directors. September 19, 2002. Available at: <http://www.cms.hhs.gov/states/letters/smd31862.pdf>. Accessed November 25, 2002.
39. U.S. General Accounting Office. State pharmacy programs. Assistance designed to target coverage and stretch budgets. Available at: <http://www.gao.gov/new.items/hw0162.pdf>. Accessed November 25, 2002.
40. Klemm JD. Medicaid spending: a brief history. Health Care Financing Review. 2003;22(1):105-112.
41. Hefelman J. Variations among states in health insurance coverage and medical expenditures: 'how much is too much?' The Urban Institute. June 2002. Available at: [http://www.urban.org/UploadedPDF/310520\\_DP0267.pdf](http://www.urban.org/UploadedPDF/310520_DP0267.pdf). Accessed October 29, 2002.
42. Klemm JD. Medicaid spending: a brief history. Health Care Financing Review. 2003;22(1):105-112.
43. National Governors Association and National Association of State Budget Officers. The fiscal survey of states. May 2002. Available at: <http://www.nasbo.org/Publications/fiscsur/may2002/fiscalsurvey.pdf>. Accessed September 23, 2002.
44. Smith V, Ellis E, Girard K, Ramesh R, Wachino V. Medicaid spending growth: a 50-state update for fiscal year 2003. Kaiser Commission on Medicaid and the Uninsured. January 2003. Available at: <http://www.kcf.org/content/2003/20030113/0082.pdf>. Accessed January 14, 2003.

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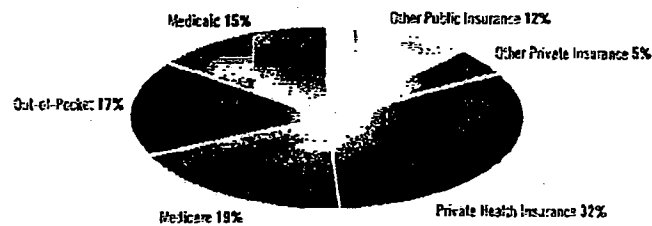


The late 1990s saw large increases in Medicaid expenditures spurred by federal and state initiatives, as well as by factors that could not be predicted, such as the AIDS epidemic. Now the largest funding source for healthcare among the poor in America, Medicaid is also among the largest part of each state's budget. After education, it is the second largest expenditure for each state, totaling, in the aggregate, an average of 19.5 percent of budgets in FY 2002.<sup>45</sup> According to a survey of state Budget Officers, the biggest contributors to recent increases in Medicaid spend are from:

- Prescription drugs
- Nursing home care
- Long-term community-based care
- Health plan payments<sup>46</sup> (see Figure B3)

Figure B3

Medicaid Spending as a Percent of All Health Spending 1998

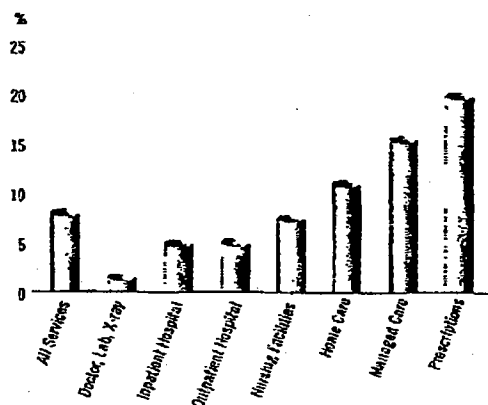


Adapted from: DePaola N-A. A profile of Medicaid. Chantock 2000. Health Care Financing Administration, U.S. Department of Health and Human Services. September 2000. Available at: <http://cms.hhs.gov/statistics/27/mtdtbl.pdf>. Accessed November 12, 2002.

45 National Governors Association and National Association of State Budget Officers. The fiscal survey of states. May 2002. Available at: <http://www.nasbo.org/Publications/fiscsurvey/may2002/fiscalsurvey.pdf>. Accessed September 23, 2002.

46 National Association of State Budget Officers and National Governors Association. Medicaid and other state healthcare issues: the current situation. May 2002. Available at: <http://www.nasbo.org/Publications/PDFs/15rmedicaidmay2002.pdf>. Accessed September 23, 2002.

Figure B4  
Growth Rates in Each Type of Expenditure 1996-2000



Adapted from: Kaiser Commission on Medicaid and the Uninsured. State budgets under stress: now are states planning to reduce the growth in Medicaid costs? July 23, 2002. Available at: <http://www.kff.org/content/2002/20020730/20020730.pdf>. Accessed October 3, 2002.

By far the biggest growing segment of almost every state's Medicaid budget is the prescription drug component. Between 1996 and 2001, Medicaid prescription drug expenditures grew by 144 percent, from \$10.2 billion in 1996 to \$24.8 billion in 2001 (See Table B1). The annual rate of growth in prescription drug spend was 9.8 percent between 1996 and 1997; then it grew annually by 20.1 percent, 18.9 percent and 20.9 percent between 1998 and 2000; and jumped by 28.6 percent in 2001. This dramatic growth in aggregate prescription drug costs is due only partially to changes in Medicaid enrollment (See Figure B4). Medicaid enrollment grew by 14.4 percent between 1996 and 2001. Because of a strong economy and new welfare work requirements, Medicaid enrollment actually declined by 4.2 percent between 1996 and 1997 and by 2.1 percent 1997 and 1998, respectively, before growing modestly through 2000. However, as economic conditions worsened and more children were served through expanded Medicaid programs, enrollment rose by 9.8 percent to 36.6 million recipients in 2001. On a PMPM basis, costs between 1996 and 2001 grew by a robust 106.4 percent, with the ebbs and flows of PMPM prescription drug costs mirroring those seen in the aggregate costs figures, indicating that the number of Medicaid recipients played a relatively minor role in this cost explosion.

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Table B1  
Total Medicaid Prescription Cost 1996-2001 (\$ in millions)

STATE	1996	1997	1998	1999	2000	2001
AK	\$22,652,912	\$27,585,094	\$34,278,068	\$44,595,460	\$56,863,656	\$71,913,702
AL	\$214,725,840	\$222,342,400	\$238,218,688	\$141,673,120	\$258,707,344	\$400,599,777
AR	\$115,935,560	\$131,949,158	\$117,689,350	\$141,572,544	\$213,908,240	\$251,966,280
AZ	N/A	N/A	N/A	N/A	N/A	N/A
CA	\$1,229,832,960	\$1,349,681,260	\$1,549,249,082	\$2,066,267,394	\$2,531,545,312	\$3,057,263,564
CO	\$62,186,532	\$50,554,620	\$111,213,928	\$129,808,040	\$112,321,016	\$129,021,184
CT	\$151,588,432	\$172,702,455	\$147,877,824	\$237,115,952	\$255,812,176	\$338,908,096
DC	\$27,676,754	\$35,702,144	\$40,721,680	\$47,227,824	\$46,394,872	\$59,115,141
DE	\$26,262,956	\$31,843,584	\$32,378,286	\$28,342,914	\$49,628,952	\$51,512,965
FL	\$644,640,128	\$757,986,644	\$894,657,216	\$1,116,200,192	\$1,341,363,040	\$1,508,140,974
GA	\$314,138,976	\$337,595,776	\$286,832,736	\$483,015,648	\$589,638,336	\$721,162,423
HI	\$30,285,568	\$31,486,158	\$38,517,096	\$32,592,148	\$56,756,284	\$32,960,635
IA	\$81,385,488	\$7,822,968	\$105,478,784	\$44,672,432	\$1,03,820,688	\$187,858,918
ID	\$33,892,738	\$40,312,228	\$26,621,974	\$53,183,064	\$76,250,104	\$98,019,666
IL	\$453,891,648	\$261,310,184	\$611,898,688	\$630,822,336	\$632,848,512	\$965,821,317
IN	\$89,154,848	\$77,445,600	\$75,495,184	\$392,639,232	\$256,746,656	\$595,203,400
KS	\$41,927,724	\$105,635,456	\$119,321,350	\$103,836,072	\$127,139,408	\$191,869,522
KY	\$300,226,112	\$327,725,696	\$321,762,016	\$379,888,480	\$506,781,408	\$652,639,896
LA	\$305,680,344	\$316,951,624	\$354,937,440	\$424,644,020	\$691,903,136	\$592,124,716
MA	\$320,861,440	\$415,687,520	\$508,334,336	\$612,308,544	\$590,727,360	\$825,119,539
MD	\$159,317,856	\$152,868,352	\$99,742,264	\$133,958,952	\$192,436,688	\$252,401,254
ME	\$176,198,544	\$183,255,952	\$129,980,758	\$149,917,544	\$179,881,904	\$205,385,605
MH	\$357,715,712	\$355,218,976	\$354,543,872	\$312,865,888	\$541,014,912	\$623,294,259
MN	\$144,381,488	\$145,414,320	\$163,401,248	\$152,487,760	\$171,119,152	\$273,026,888
MO	\$215,189,752	\$326,682,816	\$385,301,584	\$504,317,824	\$618,370,456	\$325,681,471
MS	\$173,522,096	\$130,198,312	\$216,194,000	\$67,525,068	\$278,486,560	\$469,912,904
MT	\$31,806,070	\$35,776,720	\$40,588,696	\$50,250,684	\$51,321,740	\$74,355,812
NC	\$264,482,832	\$308,883,104	\$480,707,136	\$484,610,464	\$617,920,448	\$1,018,073,252
ND	\$23,150,188	\$23,930,996	\$70,796,460	\$32,505,064	\$38,470,688	\$44,950,036
NE	\$54,684,964	\$82,186,048	\$92,787,824	\$120,912,464	\$143,845,328	\$174,798,602
NH	\$20,132,956	\$41,221,877	\$54,835,152	\$69,076,272	\$45,766,716	\$50,061,353
NJ	\$353,044,032	\$369,383,168	\$416,317,632	\$498,670,240	\$585,815,688	\$644,422,410

STATE	1996	1997	1998	1999	2000	2001
AK	\$63,177,252	\$63,520,568	\$35,257,704	\$43,470,855	\$51,427,124	\$62,619,561
AR	\$18,986,590	\$12,752,982	\$35,126,896	\$41,358,852	\$53,899,244	\$67,219,840
NY	\$977,705,216	\$1,179,280,000	\$1,578,070,420	\$2,902,225,408	\$2,431,010,204	\$2,928,637,396
OH	\$397,066,720	\$450,963,152	\$662,439,360	\$793,736,575	\$918,909,632	\$1,172,465,407
OK	\$102,554,752	\$116,453,336	\$141,473,775	\$169,218,288	\$195,678,698	\$225,318,621
OR	\$69,046,136	\$76,583,744	\$96,748,080	\$130,533,896	\$174,673,248	\$238,591,713
PA	\$421,020,432	\$533,202,456	\$550,914,816	\$175,416,112	\$313,010,720	\$704,579,608
RI	\$35,521,852	\$52,551,104	\$64,809,252	\$77,146,880	\$91,885,648	\$51,898,926
SC	\$125,836,600	\$146,390,960	\$176,463,736	\$306,586,752	\$409,135,264	\$442,694,984
SD	\$21,433,936	\$28,560,276	\$28,341,832	\$34,746,092	\$40,848,068	\$52,426,657
TH	N/A	N/A	N/A	\$150,709,552	\$376,674,208	\$728,691,310
TX	\$674,956,704	\$761,227,584	\$830,905,654	\$980,655,920	\$837,284,160	\$1,275,879,987
UT	\$47,544,024	\$52,378,992	\$75,571,005	\$84,383,304	\$74,907,552	\$114,555,945
VA	\$220,780,640	\$251,110,624	\$289,628,096	\$343,695,264	\$385,415,584	\$431,668,511
VT	\$30,756,826	\$40,902,512	\$31,321,558	\$54,796,320	\$14,604,345	\$18,322,941
WA	\$187,534,912	\$204,392,688	\$246,445,152	\$307,927,424	\$390,384,032	\$478,661,919
WI	\$189,557,904	\$203,387,690	\$235,371,472	\$291,480,896	\$351,514,592	\$399,205,236
WV	\$121,711,408	\$130,796,888	\$161,836,640	\$137,902,896	\$190,561,184	\$250,532,987
WY	\$5,439,774	\$15,179,210	\$16,026,050	\$22,568,148	\$27,455,108	\$23,795,616

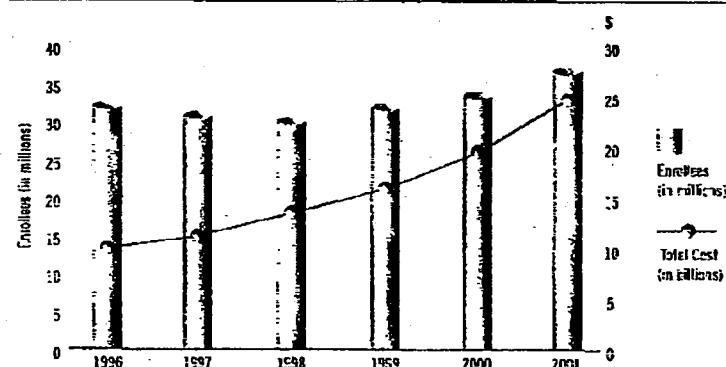
Adapted from: Medicaid Statistical Information Systems (MSIS) and HCFA-2082 State Tables. Available at: <http://cms.hhs.gov/medicaid/msis/e-stats.asp>. Accessed September 24 and 27, 2002, and October 2 and 16, 2002.

What is unknown due to lack of data is the degree to which the eligibility mix of Medicaid recipients has influenced changes in overall Medicaid prescription drug costs. It is known that SSI recipients are far sicker, and therefore higher utilizers and more costly than other Medicaid eligibility categories. It is also true that SSI recipients are much more likely to maintain their eligibility status than some other eligibility groups. Thus, as is true in the commercial sector, Medicaid prescription drug costs are fueled by higher utilization and increased cost per prescription. But assessing the relative magnitude of utilization versus cost per prescription is more difficult because of the dearth of information pertaining to drug costs by Medicaid eligibility category. Having said that, except for 2001, utilization played a lesser role in driving cost increases than did increases in the cost per prescription (see Figure 85). PMPM utilization increased by only 17 percent between 1996 and

2001. In fact, PMPM utilization actually declined in 1999, grew by less than 2.5 percent in 1997 and 2000, and rose by 8.1 percent and 9.0 percent in 1998 and 2001, respectively (see Table B2). In contrast, cost per prescription increased by over three-quarters between 1996 and 2001, annually rising between 12.4 percent and 14.0 percent from 1996 through 2000, before dropping to a 7.7 percent rate of increase in 2001.

Figure B5

Total Medicaid Prescription Drug Cost vs. Number of Enrollees 1996-2001



Adapted from Medicaid Statistical Information Systems (MSIS) and HCFA-2002 State Tables. Available at: <http://cms.hhs.gov/medicaid/msis/statstabs.asp>. Accessed September 24 and 27, 2002, and October 2 and 16, 2002.

Table B2

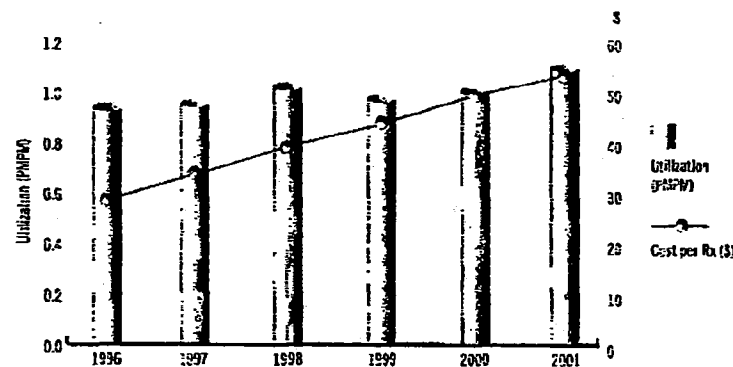
PMPM Medicaid Prescription Drug Use 1996-2001

STATE	1996	1997	1998	1999	2000	2001
AK	0.50	0.55	0.37	0.29	1.05	1.16
AL	1.32	1.29	1.28	0.68	0.91	1.19
AR	0.87	1.25	0.75	0.85	0.93	1.04
AZ	N/A	N/A	N/A	N/A	N/A	N/A
CA	0.70	0.72	0.69	0.73	0.75	0.72
CO	0.64	0.52	1.14	1.22	0.82	0.82
CT	1.15	0.37	0.89	1.23	1.23	1.21
DC	0.53	0.51	0.67	0.64	0.55	0.54
DE	0.92	1.24	0.85	0.56	0.83	0.85
FL	0.56	1.05	1.08	1.07	1.05	1.08
GA	1.19	1.16	0.81	1.17	1.35	1.32
HI	0.58	0.55	0.58	0.45	0.66	0.31
IL	1.56	1.20	1.20	0.47	0.35	1.39
IN	1.13	1.21	0.68	1.22	1.05	1.02

STATE	1996	1997	1998	1999	2000	2001
IL	1.93	0.54	1.16	1.10	1.12	1.17
IN	0.55	0.45	0.39	1.52	0.79	1.51
KS	0.56	1.41	1.52	1.08	1.17	1.56
KY	1.70	1.73	1.57	1.51	1.62	1.80
LA	1.12	1.34	1.40	1.33	1.32	1.27
MA	1.32	1.35	1.22	1.28	1.36	1.31
MD	0.83	0.76	0.41	0.48	0.34	0.57
ME	1.38	1.49	1.51	1.59	1.65	1.50
MJ	0.96	0.87	1.81	0.64	0.59	0.92
MN	0.86	0.97	0.92	0.82	0.62	0.78
MO	0.93	1.29	1.29	1.33	1.24	0.99
MS	0.91	0.82	1.13	0.28	0.76	1.05
MT	1.21	1.35	1.49	1.52	1.53	1.60
NC	0.83	0.86	1.20	1.34	1.44	1.56
ND	1.46	1.41	1.15	1.66	1.77	1.21
NE	1.21	1.63	1.53	1.55	1.59	1.61
NH	0.86	1.58	1.78	1.81	0.94	0.86
NJ	1.10	1.01	1.18	1.32	1.31	1.10
NM	0.59	0.70	0.36	0.34	0.33	0.35
NV	0.72	0.31	0.79	0.71	0.72	0.59
NY	0.88	1.09	1.33	1.25	1.33	1.29
OR	1.68	1.11	1.62	1.82	1.54	1.73
OK	0.77	0.60	0.84	0.78	0.75	0.75
OR	0.46	0.45	0.53	0.68	0.77	0.91
PA	0.70	0.82	0.90	0.24	0.42	0.83
RI	1.25	1.05	1.03	0.98	0.98	0.47
SC	0.71	0.70	0.63	0.92	1.18	0.91
SD	0.52	1.13	0.56	0.99	0.95	1.04
TH	N/A	N/A	N/A	0.25	0.60	0.56
TX	0.98	0.96	1.08	1.13	0.83	1.23
UT	1.24	1.14	1.37	1.41	1.07	1.38
VA	0.93	1.27	1.37	1.43	1.51	1.47
VT	1.00	1.24	0.60	0.95	0.21	0.22
WA	0.73	0.68	0.78	0.84	0.50	0.94
WI	1.16	1.23	1.34	1.32	1.31	1.23
WV	1.31	1.29	1.66	1.22	1.49	1.72
WY	0.52	0.73	1.24	1.20	1.18	0.82

Adapted from: Medicaid Statistical Information Systems (MSIS) and HCFA-2002 State Tables. Available at:  
<http://cms.hhs.gov/medicaid/msis/mstats.asp>. Accessed September 24 and 27, 2002, and October 2 and 16, 2002.

Figure B6  
Medicaid PMPM Utilization vs. Cost per Rx 1996-2001



Adapted from: Medicaid Statistical Information Systems (MSIS) and HCFA-2082 State Tables. Available at: <http://cms.hhs.gov/medicaid/msis/rstata.asp>. Accessed September 24 and 27, 2002, and October 2 and 16, 2002.

As one would expect, the distribution of costs is very different in the Medicaid population as opposed to the commercial sector. Medicaid basically covers high-utilizing SSI Aged, Blind and Disabled recipients on one hand, and low-utilizing women and children on the other. By comparison, the commercially insured population comprises more of a cross-section of the overall U.S. population. The distribution of Medicaid drug costs across therapy classes reflects the unique population served. After ranking second in 1996 and 1997, antipsychotics represent the most expensive therapy class for the Medicaid program (see Table B3). The proportion of cost for this class has climbed steadily from 6.9 percent of total prescription drug costs in 1996 to 12 percent in 2002. Again, not surprisingly, costs for antidepressants, anticonvulsants and antivirals are among the top therapy classes in terms of costs over most of the period. Together, these classes accounted for 17.8 percent of the 2001 Medicaid drug spend. Finally, the proportion of total prescription drug costs attributable to antidiabetic and antiasthmatic classes has grown to a combined 8.8 percent in 2001.

Table B3  
Percent of Total Cost by Therapy Class, Medicaid vs. Commercial Population

Therapy Class	Medicaid						Commercial
Name	1995	1997	1998	1999	2000	2001	2001
Antipsychotics	6.9%	8.3%	10.1%	11.0%	11.4%	12.0%	1.1%
Antidepressants	6.3%	7.1%	7.6%	7.9%	8.6%	7.9%	0.6%
Gastrointestinals	9.4%	9.2%	8.4%	7.7%	7.9%	7.1%	0.2%
Anticonvulsants	4.6%	4.9%	5.1%	5.3%	5.5%	5.6%	2.2%
Antibiotics	3.0%	4.6%	5.2%	5.3%	4.8%	4.4%	2.1%
Antidiabetics	3.1%	3.4%	3.6%	3.7%	4.0%	4.4%	4.5%
Antihistamines	4.5%	4.1%	3.8%	3.7%	3.7%	4.4%	3.8%
Anti-Rheum (NSAIDs)	3.1%	2.7%	2.4%	3.3%	4.2%	4.1%	4.9%
Narcotic Analgesics	2.7%	2.8%	2.9%	3.2%	3.5%	3.8%	2.7%
Antihyperlipidemics	2.3%	2.7%	2.9%	3.0%	3.3%	3.6%	8.3%
Antihypertensives	4.2%	3.8%	3.9%	3.8%	3.7%	3.5%	5.4%
Calcium Blockers	5.2%	4.6%	4.0%	3.4%	3.0%	2.6%	2.6%
Misc. Hematologicals	1.9%	1.5%	1.8%	1.8%	1.9%	2.1%	0.7%
Dermatologicals	3.2%	2.8%	2.6%	2.4%	2.2%	2.0%	3.1%
Antibacterials	1.4%	1.3%	1.4%	1.6%	1.8%	2.0%	3.7%
Misc. Endocrines	1.1%	1.4%	1.7%	2.0%	2.1%	2.0%	2.9%
Anticancer	1.5%	1.6%	1.6%	1.5%	1.5%	1.6%	2.2%
Anticancer Agents	1.7%	1.6%	2.0%	2.1%	1.9%	1.6%	1.1%
Hemostatic Agents	1.7%	1.6%	1.5%	1.6%	1.6%	1.4%	0.7%
Ophthalmic Products	1.4%	1.4%	1.3%	1.3%	1.2%	1.2%	1.1%
Penicillins	1.9%	1.7%	1.4%	1.3%	1.2%	1.2%	1.6%
Oral Contraceptives	1.2%	1.1%	1.2%	1.2%	1.2%	1.1%	1.5%
Stimulants/Weight Loss	0.9%	0.8%	0.8%	0.8%	0.8%	1.0%	1.0%
Cephalosporins	2.7%	2.2%	1.7%	1.4%	1.1%	1.0%	1.0%
Macrolides	1.5%	1.5%	1.3%	1.2%	1.0%	0.9%	1.5%
Other	22.4%	20.7%	19.7%	18.8%	17.6%	17.6%	23.6%

Indicates the top 10 therapy classes in terms of expenditures.

Adapted from: Medicaid Statistical Information Systems (MSIS) and HCFA-2002 State Tables. Available at: <http://cms.hhs.gov/medicaid/msis/msisets.asp>. Accessed September 24 and 27, 2002, and October 2 and 16, 2002, and from Express Scripts, Inc.

In contrast, of the top 10 classes in terms of Medicaid drug spend, only six (gastrointestinals, antidepressants, antihyperlipidemics, narcotic analgesics, antihistamines and NSAIDs) are among the top 10 commercial therapy classes in terms of expenditures. The most pronounced differences between the commercial and Medicaid cost patterns are in antipsychotics, anticonvulsants and antivirals. Medicaid expenditures for antipsychotics are almost 12-fold higher than among commercial plans (12.1 percent versus 1.1 percent), and over twice as high for anticonvulsants and antivirals (5.5 percent and 4.4 percent versus 2.2 percent and 2.1 percent, respectively). Commercial spending for antihyperlipidemics, antihypertensives, dermatologicals and antihistamines is higher than in the Medicaid population.



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### Maximizing the Federal Share of Medicaid Spending and Controlling Costs

The federal government does not place limits on the amount a state can spend on Medicaid, but states are required to spend their own funds to qualify for federal matching. It is in a state's best interest, then, to direct as much state money as feasible into Medicaid services, and thereby maximize federal matching dollars.

Despite their efforts to maximize federal funding, the states' total estimated Medicaid spending for FY 2002 was still about \$2.8 billion over budget.<sup>47</sup> At least 40 states experienced significant revenue deficits,<sup>48</sup> including unexpected Medicaid shortfalls. Most states and territories exempted Medicaid from mid-year 2002 budget cuts,<sup>49</sup> opting instead for short-term solutions, such as using tobacco settlement money.<sup>50</sup> Many states have now depleted their one-time reserve funding, and most state revenues are still falling.

Like other sectors of state government, therefore, Medicaid agencies are being forced to reduce expenses. When a state cuts Medicaid costs, though, it must balance the risks with the gains. It loses some federal matching money, but at the same time it also loses the ability to influence the use of health services by individuals who leave the Medicaid system.<sup>51</sup> Reductions in administrative staff could mean delays in beginning service for newly-eligible persons, in authorizing services for enrollees and in paying providers. Reduced payment schedules may force some providers to discontinue treating Medicaid patients. The numbers of people with no healthcare coverage and no access to preventive healthcare are likely to go up, potentially putting extra strain on emergency departments, county and local health facilities, and private charities.

47 National Association of State Budget Officers and National Governors Association. Medicaid and other state healthcare issues: the current situation. May 2002. Available at: <http://www.nasbo.org/Publications/PDFs/fsmcicaidmay2002.pdf>. Accessed September 25, 2002.

48 National Governors Association and National Association of State Budget Officers. The fiscal survey of states. May 2002. Available at: <http://www.nasbo.org/Publications/fscsur/may2002fiscalsurvey.pdf>. Accessed September 23, 2002.

49 National Governors Association and National Association of State Budget Officers. The fiscal survey of states. May 2002. Available at: <http://www.nasbo.org/Publications/fscsur/may2002fiscalsurvey.pdf>. Accessed September 23, 2002.

50 Smith V, Elms E. Medicaid budgets under stress: survey findings for state fiscal year 2000, 2001 and 2002. Kaiser Commission on Medicaid and the Uninsured. October 2001. Available at: <http://www.kff.org/content/2001/4022/4023.pdf>. Accessed October 3, 2002.

51 Kaiser Commission on Medicaid and the Uninsured. State budgets under stress: how are states planning to reduce the growth in Medicaid costs? July 30, 2002. Available at: <http://www.kff.org/content/2002/2022/2022733/20020733.pdf>. Accessed October 3, 2002.

**Strategies to Reduce Spending on Prescription Drugs**

Just as private plans adopt strategies to minimize prescription drug spending, Medicaid programs can also implement a number of cost management approaches. Among the most familiar are:

- Retail Pharmacy Discounts
- Drug Utilization Review (DUR)
- Formularies/Preferred Drug Lists with Supplemental Rebates
- Mandatory Generics
- Prior Authorization
- Quantity Limits
- Step Therapy
- Disease Management<sup>52</sup>

Some states are beginning to experiment with other methods, such as mail service pharmacy and tiered copayments.<sup>53</sup>

According to survey information released in January 2003 by the Kaiser Commission on Medicaid and the Uninsured, about half of the states are pursuing ways to curb their costs for prescription drugs under Medicaid. Twelve state Medicaid agencies say that they will require prior authorization for more drugs; nine are beginning or extending lists of preferred products; eight are seeking higher discounts for their prescription drug purchases; seven are establishing or raising participant copayments; five are asking pharmaceutical manufacturers for supplemental rebates; and two are requiring generics. Nine states will be using additional strategies such as limited days' supplies, step therapy and stricter maximum allowable cost (MAC) lists. Despite poor results from previous similar restrictions, five states are also re-imposing limits on the number of prescriptions that can be filled per given time period.<sup>54</sup>

Paradoxically, a number of states have made recent changes to their Medicaid programs in an effort to increase coverage for prescription drugs. Under section 1115 waivers, some states are testing "Pharmacy Plus" strategies that extend a prescription drug benefit to low-income seniors and disabled adults who are not otherwise eligible for Medicaid. More than 30 states have similar, self-funded plans — many probably will apply for a waiver in order to get the federal match.<sup>55</sup>

52 Smith V, Ellis E, Gifford K, Ramesh R, Wachino V. Medicaid spending growth: a 50-state update for fiscal year 2002. Kaiser Commission on Medicaid and the Uninsured, September 2002. Available at: <http://www.kff.org/content/2003/20030113/4082.pdf>. Accessed January 14, 2003.

53 National Conference of State Legislatures. Recent Medicaid Prescription Drug Laws and Strategies, 2001-2003. Updated February 5, 2003. Available at: <http://www.ncsl.org/programs/health/mcdicaidcr.htm>. Accessed February 25, 2003.

54 Smith V, Ellis E, Gifford K, Ramesh R, Wachino V. Medicaid spending growth: a 50-state update for fiscal year 2003. Kaiser Commission on Medicaid and the Uninsured, January 2003. Available at: <http://www.kff.org/content/2003/20030113/4082.pdf>. Accessed January 14, 2003.

55 Smith V, Ellis E, Gifford K, Ramesh R, Wachino V. Medicaid spending growth: results from a 2002 survey. Kaiser Commission on Medicaid and the Uninsured, September 2002. Available at: <http://www.kff.org/content/2002/4064/4064.pdf>. Accessed October 3, 2002.

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Waivers take two distinctive forms:

**Subsidies:**

Typified by the Illinois SeniorCare Rx program, subsidy-type plans use state and federal funding to cover medications for low- and moderate-income elderly state residents whose income is up to 200 percent of the FPL. Based on their incomes, recipients pay a minimal annual fee and/or a small copayment for each prescription.<sup>55</sup>

**Discount Only:**

The Healthy Maine Prescription Program, for example, would allow any Maine resident with an income below 300 percent of the current federal poverty limit to buy prescription drugs at the same discounted prices in effect for Medicaid recipients. Although the state would incur some small expense with the plan, the majority of the cost would rest on the users of the benefit.<sup>57</sup> As the result of legal actions, however, the Healthy Maine Prescription Program and similar plans in other jurisdictions have been suspended. A decision from the U.S. Supreme Court will decide whether states can extend drug benefits to non-Medicaid recipients.

**Summary**

Since its beginning in 1965, the Medicaid program has grown dramatically in terms of enrollment, scope of covered services and costs. Prescription drugs are among the program services for which costs have grown most substantially. As states try to deal with severely decreasing revenues and rapidly increasing Medicaid costs, they will have to become much more aggressive in controlling higher prescription drug costs. To help meet their budget needs and still provide adequate services, state Medicaid agencies are beginning to adopt many of the approaches used by the private sector to contain prescription costs.

55 National Conference of State Legislatures, States and "pharmacy plus" Medicaid waiver options, Updated November 11, 2002. Available at: <http://www.ncsl.org/programs/health/pharmplus.html>. Accessed November 14, 2002.

57 Centers for Medicare and Medicaid Services, U.S. Department of Health and Human Services, Fact Sheet, Maine 1:15 pharmacy demonstration. No Date Given. Available at: <http://cms.hhs.gov/medicaid/1115/mets.pdf>. Accessed November 26, 2002.

**NOTES**

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**EXPRESS SCRIPTS DRUG TREND REPORT**

(Please copy and fax or mail back.)

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	2001 Drug Trend Report – June 2002 (\$100 per copy)	
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# **Exhibit 6W**

Roe CM, McNamara AM, Motheral BR. Gender- and age-related prescription drug use patterns. *The Annals of Pharmacotherapy*. 2002;36(1):30-39.

The purpose of the study was to summarize gender- and age-related prescription drug utilization patterns among a large, diverse, commercially-insured population within the United States. Results indicated that most gender differences in medication use appear after or around the puberty years. Women were more likely to use several classes of medications, including antidepressants, and anti-anxiety and pain medications.

Roe CM, Anderson MJ, Spivack B. How many patients complete an adequate trial of donepezil? *Alzheimer Disease and Associated Disorders*. 2002;16(1):49-51.

Pharmacy claims data were used to examine medication adherence among 59 new users of donepezil, aged 65 to 94 years. The study found that the probability of a new user continuing donepezil at 90 days was  $0.797 \pm 0.103$  and at 180 days was  $0.627 \pm 0.124$ . Caps in treatment of six weeks or more were seen for 13.9% of those who continued therapy for at least 180 days.

Motheral BR, Cox ER, Mager DE, Henderson RR. 2000 *Prescription Drug Atlas*, January 2002.

This study is the first comprehensive state-by-state study of prescription drug use. Age and gender have always been among the best indicators of prescription drug use, but results from this study show that where one lives is also a good indicator of which and how many medications one uses. Prescription drug use was tracked for a random sample of commercially-insured members who were continuously enrolled throughout 2000. Results showed that general prescription drug use was lower in the Northeast and West, and higher in the South and Midwest. Even greater variation was found upon examination of prevalence of prescription drug use for 23 of the most commonly-prescribed therapy categories. The study also observed prescription use for children and found that overall, children exhibited greater variation than adults for most therapy classes.

162 express scripts

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## Research Studies

### PHARMACY BENEFIT DESIGN

Delate T, Henderson RR, Motheral BR. Financial impact of benefit design choice for non-sedating antihistamines. January 2004.

All forms and strengths of Claritin — a prescription non-sedating antihistamine (NSA) — became available for sale over-the-counter (OTC) in December 2002. With these products going OTC, other prescription NSAs remaining on the market and no generic prescription Claritin products offered, health plans had a number of trend-management options available for OTC Claritin and the prescription NSA products. This study presents an evaluation of the financial impact on health plan decisions regarding NSA coverage.

*This study is available at [www.express-scripts.com](http://www.express-scripts.com).*

Fairman KA, Motheral BR, Henderson RR. Retrospective, long-term follow-up study of the effect of a three-tier prescription drug copayment system on pharmaceutical and other medical utilization and costs. *Clinical Therapeutics*. 2003;25(12):3147-3161.

The purpose of this study was to examine the effect of a three-tier copayment system on pharmaceutical and medical utilization and cost for 30 months after implementation in a population of commercially insured, preferred-provider organization members. Results showed reduced growth in net cost and lower utilization of third-tier medications. The intervention and comparison groups did not differ significantly with respect to numbers of office visits, emergency department visits or inpatient hospitalizations.

Roe CM, Heinle SM, Cox ER. Design of a three-tier benefit and cost trend. *Drug Benefit Trends*. 2002;14(8):21-26.

This study explores how the design of a three-tier prescription benefit is correlated to drug trend. Pre- to post-period change in payer cost was examined for 20 plans that switched from a two-tier to a three-tier copayment design. Pre- to post-period trends in per member per month net costs decreased as the aggressiveness of the three-tier structure — measured by the average pre- to post-dollar copayment per prescription — increased. This study suggests that more aggressive three-tier structures are associated with lower net cost trend.



## RESEARCH STUDIES

## COST-EFFECTIVENESS OF PHARMACEUTICALS

Cox ER, Motheral BR, Mager D. Verification of a decision analytic model assumption using real-world practice data: implications for the cost effectiveness of cyclo-oxygenase 2 inhibitors (COX-2s). *The American Journal of Managed Care*. 2003;9(12):785-794.

This study evaluated the gastroprotective agent (GPA) rate assumption used in model cost-effectiveness for COX-2s and to re-estimate model outcomes using GPA rates from actual practice. This study found the rate of GPA use is positive and marginally higher among COX-2 users than among nonselective NSAID users. Findings suggest a re-evaluation of COX-2 cost effectiveness models is warranted.

Cox ER, Motheral BR, Frisse M, Behm A, Mager D. Prescribing COX-2s for patients new to cyclo-oxygenase inhibition therapy. *The American Journal of Managed Care*. 2003;9(11):735-742.

The purpose of this study was to profile the pattern of COX-2 use, including length of therapy, medical conditions treated and gastrointestinal risk. Findings suggest that opportunities exist to encourage the cost-effective prescribing of COX-2 therapy.

Fairman KA, Motheral BR. Do decision-analytic models identify cost-effective treatments? A retrospective look at *Helicobacter pylori* eradication. *Journal of Managed Care Pharmacy*. 2003;9(5):430-440.

The purpose of this study was to examine retrospectively whether *H. pylori* pharmacoeconomic models direct decision makers to cost-effective therapeutic choices. Model assumptions were replaced with empirical data from a multi-payer claim database, and it was determined that model results overstated the cost effectiveness of PPI-clarithromycin and understated the cost effectiveness of bismuth-metronidazole-tetracycline (BMT).

## POPULATION HEALTH AND PHARMACEUTICALS

Delate T, Gelenburg AJ, Simmons VA, Motheral BR. Trends in the use of antidepressant medications in a nationwide sample of commercially insured pediatric patients, 1998-2002. *Psychiatric Services*. 2004; 55(4):387-391.

The purpose of this study was to determine contemporary estimates of the prevalence of ambulatory antidepressant medication (ADM) use in commercially-insured children and adolescents. Results indicated that the growth in the prevalence of ADM use in these populations appears to be continuing, similar to growth seen earlier in the era of the second generation ADMs.

Delate T, Simmons VA, Motheral BR. Patterns of use of sildenafil among commercially-insured adults in the United States: 1998-2002. *International Journal of Impotence Research*. (In Press)

The purpose of this study was to profile sildenafil (Viagra®) use in the United States. The percentage of Express Scripts members who used sildenafil increased substantially from 1998 to 2002. The fastest growing segment of users was males aged 18 to 45 years, the current target of direct-to-consumer advertising. The proportion of users with an underlying medical reason declined in all age groups over the five years. The finding that the number of sildenafil tablets dispensed per prescription over the study period remained stable suggests that plan sponsor use of benefit strategies can help manage the trend for this therapy class.

Cox ER, Motheral BR, Henderson RR, Mager D. Geographic variation in the prevalence of stimulant medication use among children 5 to 14 years old: Results from a commercially insured US sample. *Pediatrics*. 2003;111(2):237-243.

This study evaluated geographic variation in the use of stimulant medications in a sample of commercially-insured children aged 5 to 14 years. The study also evaluated other factors thought to influence the use of stimulants in children including age, gender, income and urban/rural residence. The study found significant variation in use of stimulants across geographic regions, with higher use in the South and Midwest, compared to the Western region of the country.

## RESEARCH STUDIES

Roe CM, Odell KW, Henderson RR. Concomitant use of antipsychotics and drugs that may prolong the QT interval. *Journal of Clinical Psychopharmacology*. 2003;23(2):197-200.

The purpose of this study was to compare the concomitant use of drugs that may prolong the QT interval. One group of patients used antipsychotics that may cause QT prolongation and one group of patients used antipsychotics that do not prolong the QT interval. This study indicated there was no significant difference between the two groups with concomitant use of other QT drugs when potential confounders were controlled.

Teitelbaum E, Parker AR, Frear RS, Vargas SL. The change in the use of hormone replacement therapies (HRT) combination products, estrogens and other agents used to treat osteoporosis since the release of HERS II and WHI findings. January 2003.

In July 2002, the *Journal of the American Medical Association* published two studies questioning the relative safety of combination estrogen/progestin HRT products. To assess physician and member reaction to these studies, Express Scripts researchers analyzed the use of combination HRT products before and after the issuance of the HERS II and WHI information. More specifically, Express Scripts addressed the extent to which the use of the HRT combination products Prempro® and Premphase®, estrogens, and other agents (such as Evista®, Fosamax® and Actonel®) used to treat osteoporosis changed after these highly publicized studies were released.

This study is available at [www.express-scripts.com](http://www.express-scripts.com).

160 express scripts

Cox ER, Henderson RR. Prescription use behavior among Medicare beneficiaries with capped prescription benefits. *Journal of Managed Care Pharmacy*. 2002;5(8):360-364.

The purpose of this study was to evaluate the strategies Medicare beneficiaries adopt to manage their out-of-pocket prescription drug costs in a plan with capped annual prescription drug benefits of \$500 or \$1,000. A total of 786 surveys were mailed to Medicare-Choice members. Of the 28% response rate, 70% of respondents participated in at least one strategy -- obtaining samples from their physicians, for instance -- to manage prescription drug costs. This strategy raises the question of whether prescription drug samples may discourage the prescribing of lower-cost therapeutic alternatives.

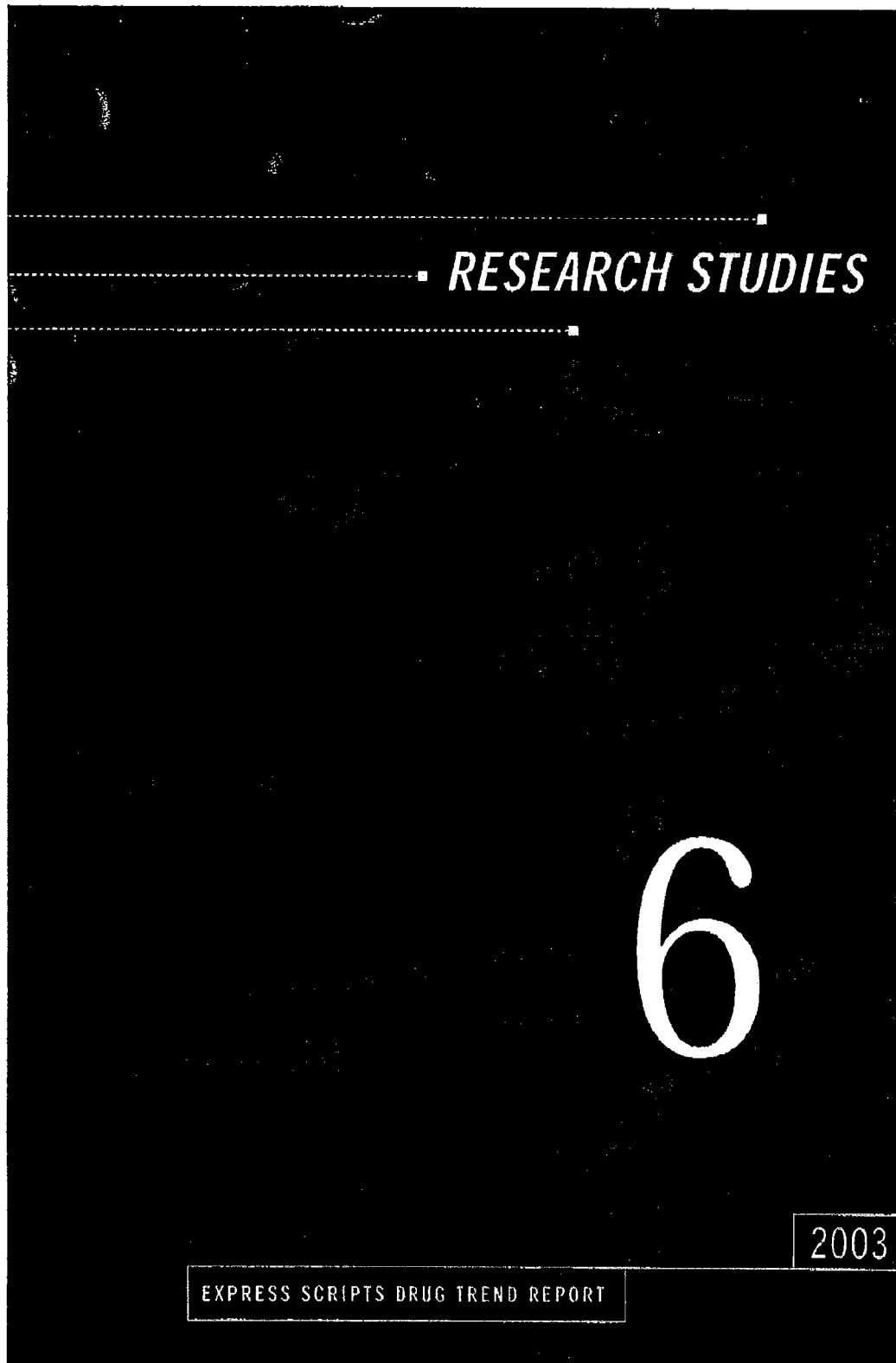
Roe CM, Anderson MJ, Spivack B. Use of anticholinergic medications among older adults with dementia. *Journal of the American Geriatrics Society*. 2002;50:836-842.

The purpose of this study was to compare the prevalence of anticholinergic use among older adults with probable dementia and to examine the extent to which patients taking donepezil concomitantly use anticholinergic medications. This study found that community based, commercially-insured, older adults with probable dementia are more likely to be exposed to anticholinergics than matched controls. Patients taking donepezil frequently use an anticholinergic medication concomitantly.

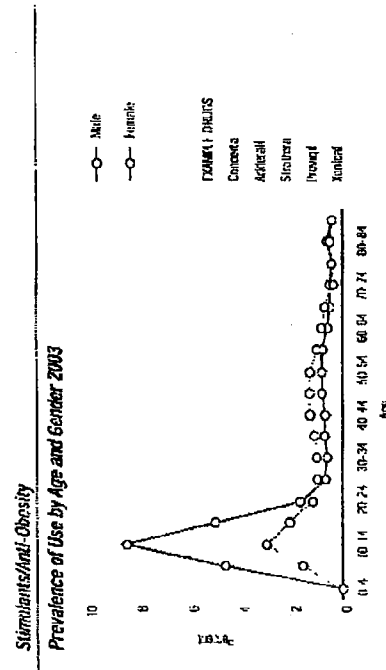
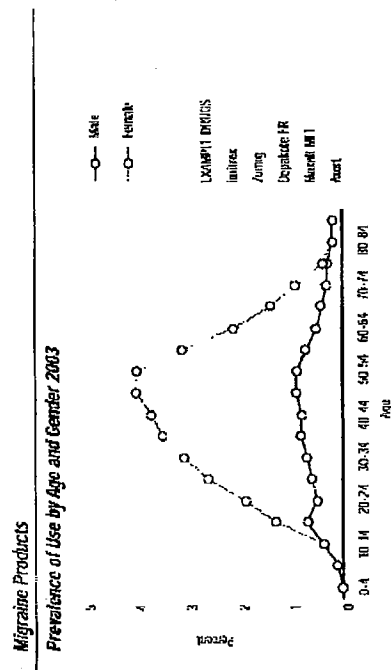
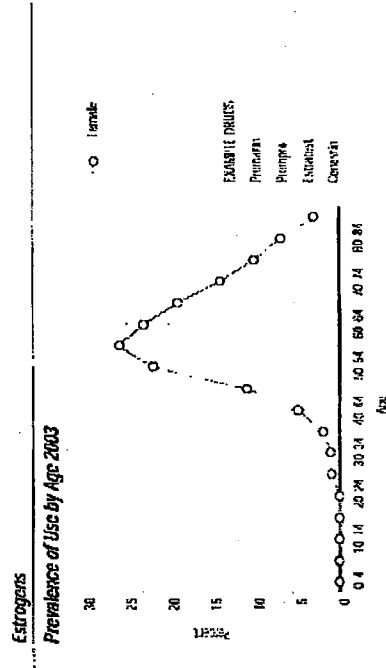
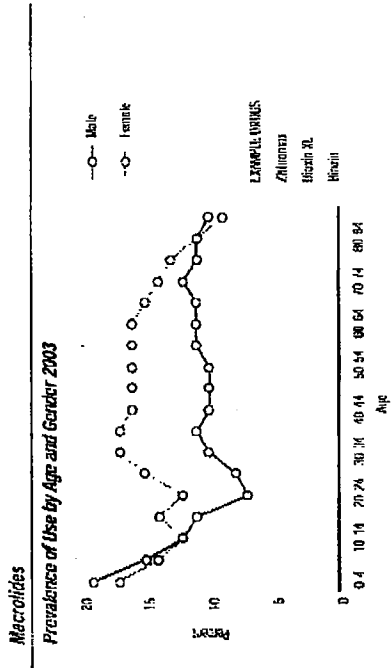
Roe CM, McNamara AM, Motheral BR. Use of chronic medications among a large, commercially-insured US population. *Pharmacoepidemiology and Drug Safety*. 2002;11(4):301-309.

This study examined how medications for chronic conditions are used in everyday life. Results showed that females were more likely than males to use chronic medications during the study year and that commonly-used chronic medications accounted for 53% of total drug costs for both sexes. Generally, the likelihood of using a chronic medication increased with age for both sexes. Additionally, of those who took chronic drugs, 14% used combination chronic therapy.

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## AGE AND GENDER APPENDIX



AGE AND GENDER APPENDIX

*Notes*

156 express scripts

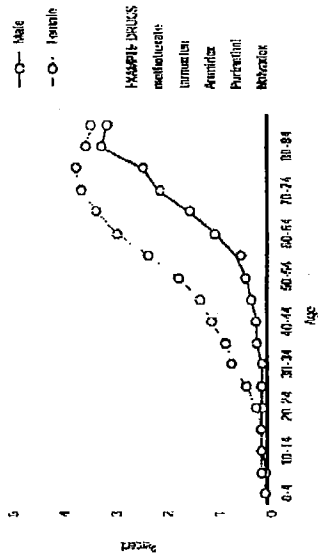
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## AGE AND GENDER APPENDIX

## AGE AND GENDER APPENDIX

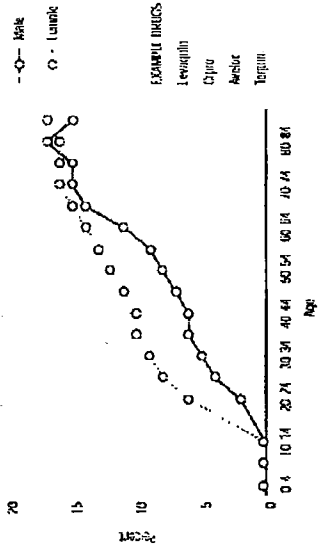
## Antineoplastics

Prevalence of Use by Age and Gender 2003



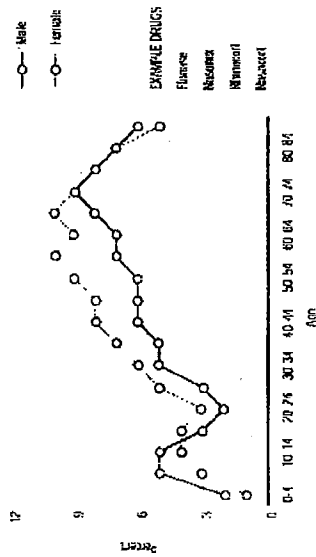
## Quinolones

Prevalence of Use by Age and Gender 2003



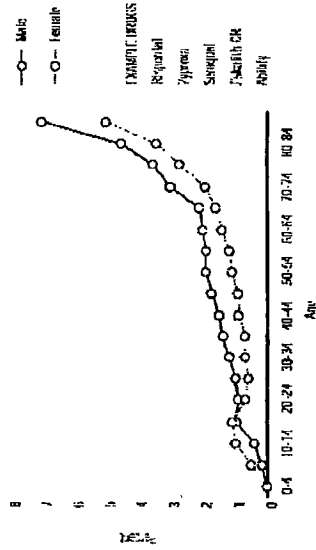
## Decongestants

Prevalence of Use by Age and Gender 2003

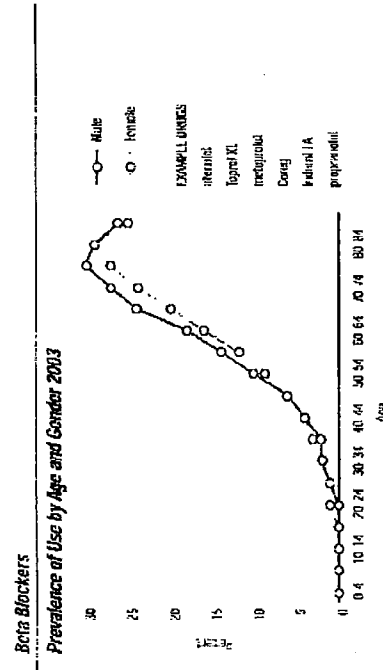
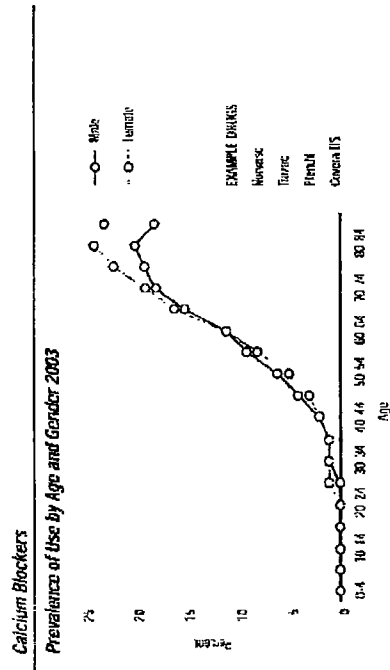
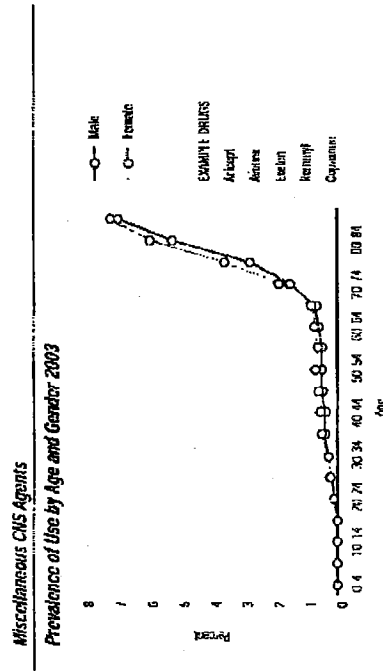
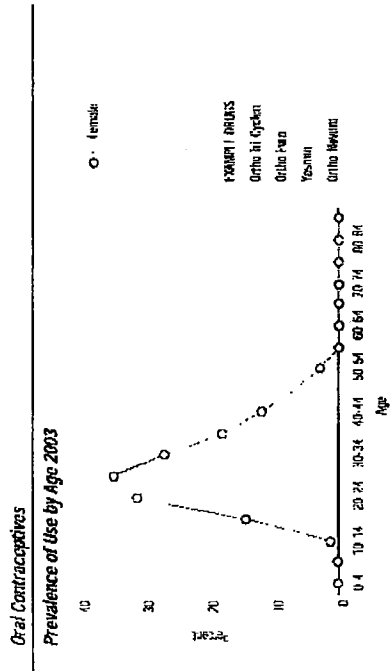


## Antipsychotics

Prevalence of Use by Age and Gender 2003



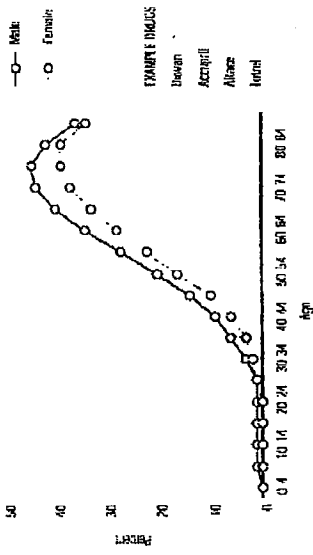
## AGE AND GENDER APPENDIX



## AGE AND GENDER APPENDIX

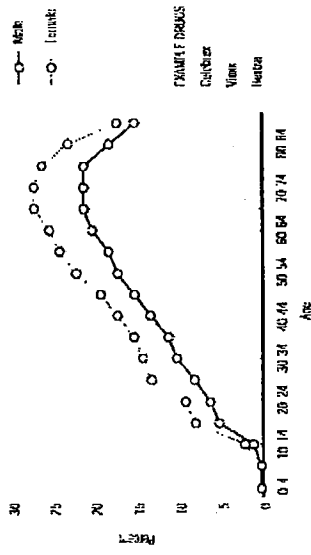
## Antihypertensives

## Prevalence of Use by Age and Gender 2003



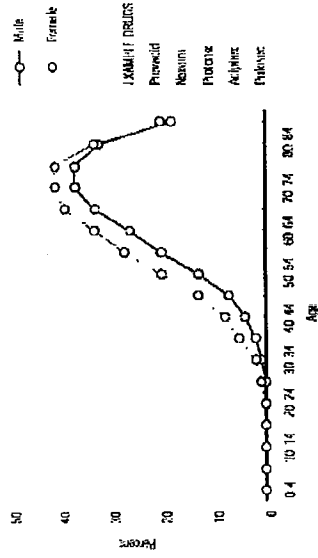
## Anti-Rheumatics (NSAIDs)

## Prevalence of Use by Age and Gender 2003



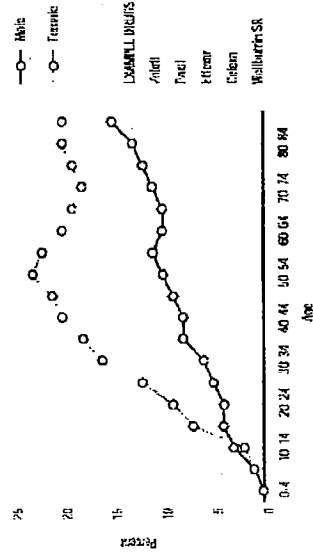
## Gastrointestinals

## Prevalence of Use by Age and Gender 2003



## Antidepressants

## Prevalence of Use by Age and Gender 2003

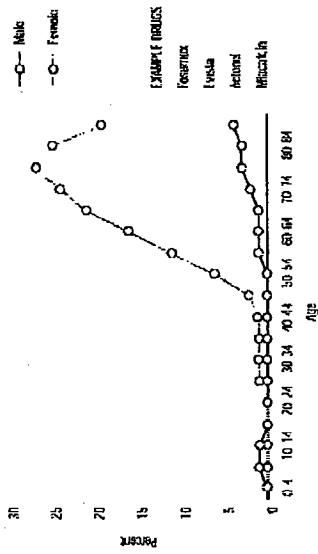




## AGE AND GENDER APPENDIX

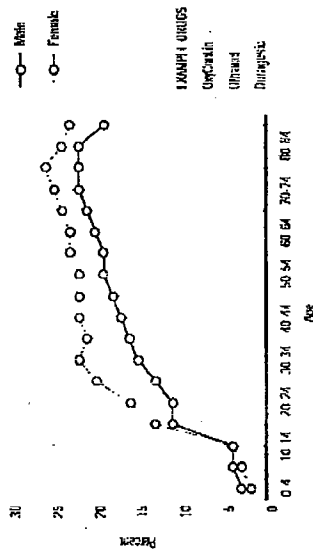
## Miscellaneous Endocrines

Prevalence of Use by Age and Gender 2003



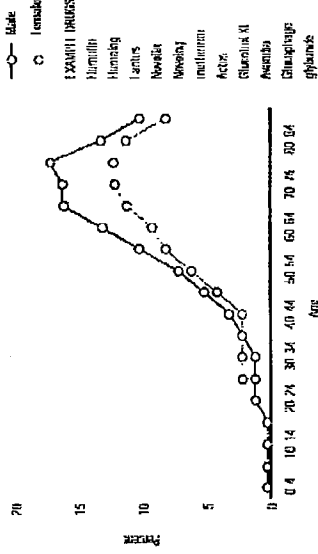
## Narcotic Analgesics

Prevalence of Use by Age and Gender 2003



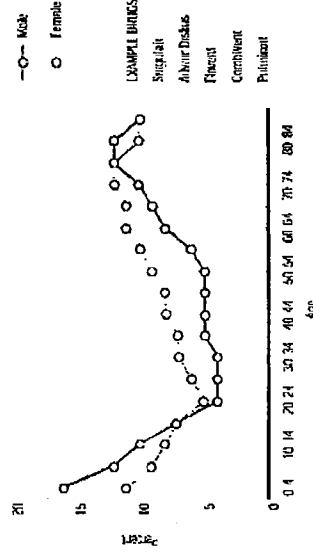
## Antidiabetics

Prevalence of Use by Age and Gender 2003

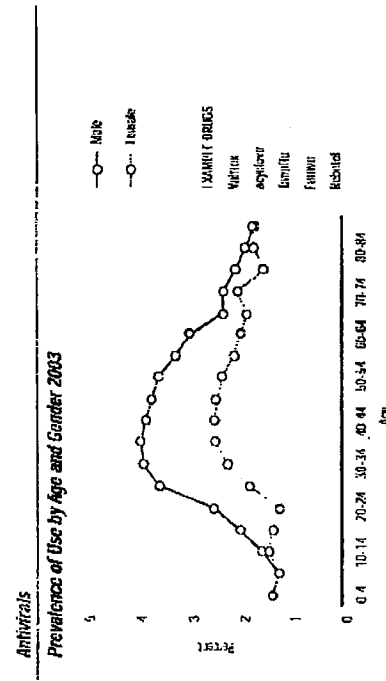
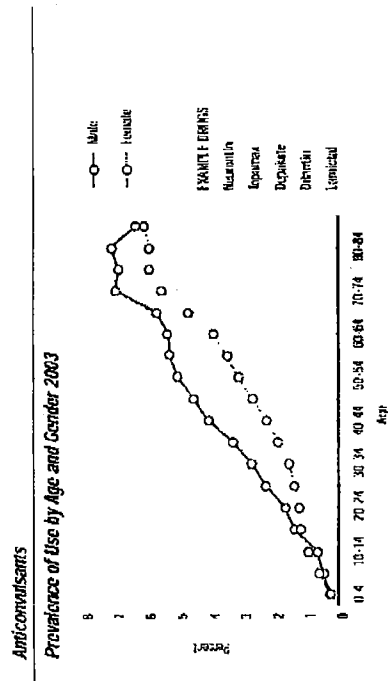
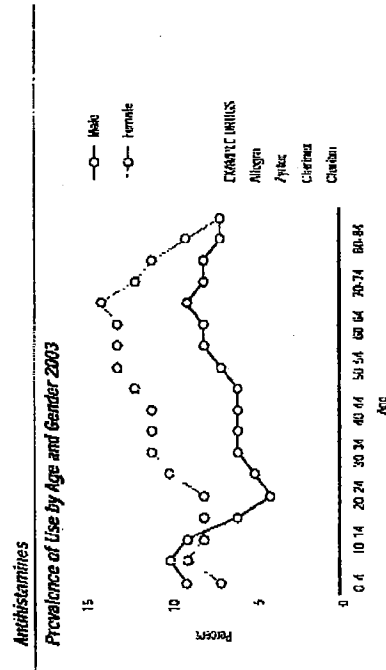
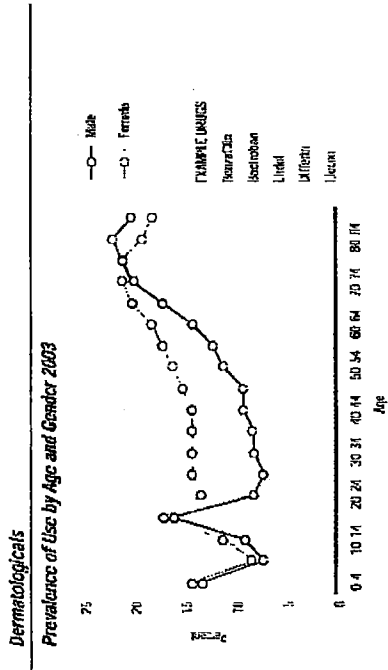


## Antihistamines

Prevalence of Use by Age and Gender 2003



## AGE AND GENDER APPENDIX



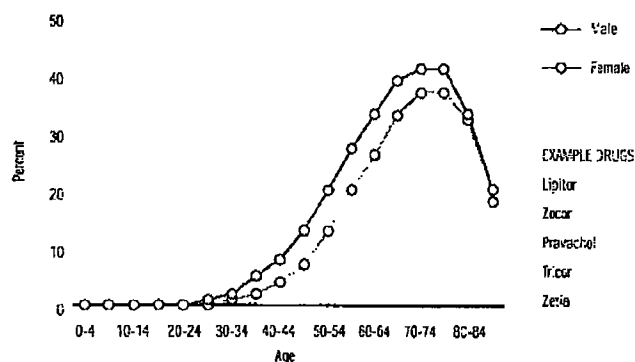
## Drug Prevalence by Age and Gender

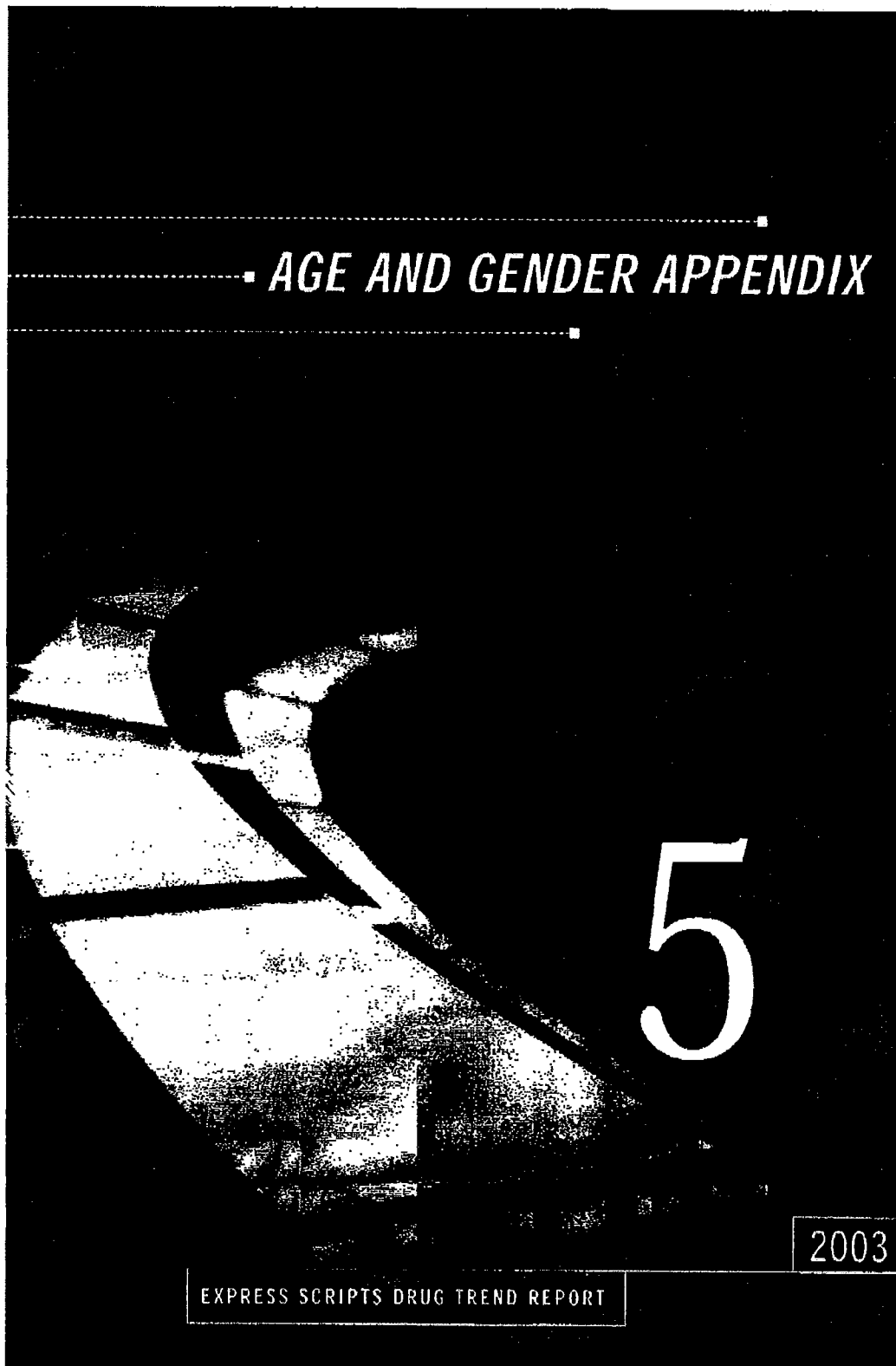
This appendix to the 2003 *Drug Trend Report* presents the prevalence of use by age and gender for the top 25 therapy classes ranked by cost. The sample of members used to determine prevalence and to create these charts was the same sample of 2.1 million members whose prescription use was analyzed to determine overall trend from 2002 to 2003. These members belonged to groups offering a funded benefit that allowed members to use either retail or mail pharmacies. Members belonging to groups with Medicare or Medicaid benefits were excluded.

For the purpose of this appendix, prevalence was defined as the percentage of eligible members who filled at least one prescription in the therapy class during 2003. Age was determined by the member's age on the last day of 2003.

### Antihyperlipidemics

#### Prevalence of Use by Age and Gender 2003





PHARMACY BENEFIT GUIDE

*Notes*

142 express scripts

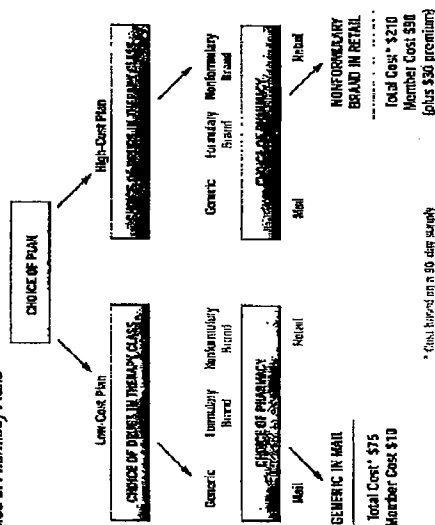
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## PHARMACY BENEFIT GUIDE

For organizations moving from one general approach to another (e.g., traditional to member incented), transitional plan designs can be used to facilitate the change. A common scenario for plan sponsors with open formularies and minimal use of POS programs is continued double-digit growth in pharmaceutical expenditures. While plan sponsors facing this scenario often desire to control drug expenditures more effectively, they may hesitate to implement changes due to concern about negative impact on employee-employer relationships. When challenged with the need to balance trend-management activities carefully with employee relationships, plan sponsors move to a member-incented approach and still maintain member satisfaction. One solution is to offer members a choice of pharmacy benefits.

Specifically, in this scenario, the plan sponsor could offer two plans: its existing benefit and an incentive-based, three-tier benefit. Monthly premiums for the existing benefit would be higher than premiums for the three-tier benefit, with the specific amount depending on the actuarial difference in cost between the two plans. Each member then chooses the plan he or she prefers. The plan sponsor will begin to experience savings as some members select the three tier design and as manufacturer volume discounts increase on formulary brands.

## Choice in Pharmacy Plans



\* Cost based on a 90 day supply

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## Plan-Design Characteristics for Each Approach

	Traditional	Member-Incented	Basic-Coverage
<b>COST-SHARING</b>			
Member Cost-Sharing	20%-30%	25%-35%	20%-30%
Copayment Structure	Two-Tier	Three-Tier	Two-Tier/Closed Formulary
Tier 1	Generics	Generics	Formulary
Tier 2	Brands	Formulary Brands	Formulary Brands
Tier 3	N/A	Nonformulary Brands	N/A
Copayment Amounts			
Generics	\$5-\$10	\$5-\$10	\$5-\$10
Formulary Brands	\$15-\$30	\$15-\$25	\$15-\$30
Non-formulary Brands			
Copayment	\$15-\$30	\$30-\$50	100% cost-share
Differences	At least \$8 between generic and formulary brand copayments	At least \$8 between generic and formulary brand copayments and at least \$15 between formulary brand and non-formulary brand copayments	At least \$8 between generic and formulary brand copayments
Generic Policy	Mandatory	Mandatory	Mandatory
<b>DRUG COVERAGE</b>			
Refill Restriction	Yes: 34-day supply per refill at retail	Yes: 34-day supply per refill at retail	Yes: 34-day supply per refill at retail
Quantity Limits	Basic: to safeguard against typos and fraud	Basic and Expanded: to ensure dosing within clinical guidelines	Basic and Expanded: to ensure dosing within clinical guidelines
Formulary	100% of drugs covered	80% of drugs covered at Tier 1 or Tier 2 amounts	60%-70% of drugs covered at Tier 1 or Tier 2 amounts
Prior Authorization	Administrative only (i.e., just medication, going on vacation)	Administrative and clinical: includes drugs with significant potential for inappropriate use	Administrative and clinical: includes drugs with significant potential for inappropriate use
Step Therapy	No	Yes	Yes
Injectables	Specialty Distribution	Specialty Distribution	Specialty Distribution

140 express scripts

## PHARMACY BENEFIT GUIDE

**TRADITIONAL APPROACH**

Plan sponsors with reservations about asking members to take responsibility for using cost-effective medications (because of employee retention or other reasons) choose plan designs that provide the broadest drug coverage. This traditional approach, used most frequently in the past, has few financial incentives to encourage optimal use.

**MEMBER-INCENTED APPROACH**

For plan sponsors with more interest or latitude in managing expenditures, the member-incented approach is commonly used because it combines financial incentives with information that helps members make informed choices about their prescription drug use. The economically incented approach not only gives members a high degree of choice, it also rewards members for choices that help contain costs (e.g., use of formulary medications). Plans that adopt this approach leave the same number of drugs on the formulary but ask members to pay more for nonformulary drugs.

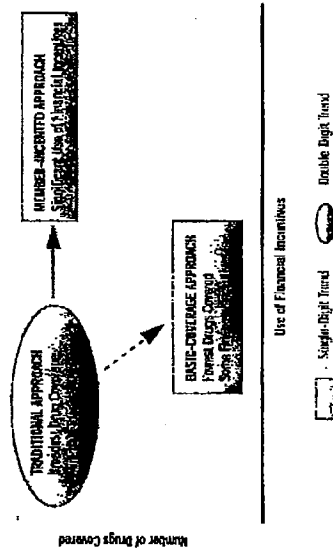
**BASIC-COVERAGE APPROACH**

Finally, plan sponsors who want to manage drug trend aggressively use what is termed the basic-coverage approach. More restrictive than the member-incented approach, the basic-coverage approach places more limits on what drugs are covered. In other words, the plan sponsor says no to coverage of nonformulary drugs instead of relying on the patient to choose, as with the member-incented approach. While fewer drugs are covered under a basic-coverage approach, the opportunity for long-term trend management is maximized.

Exhibit 43 provides more detail on the main designs for each approach.

**Plan Design: Developing an Action Plan**

While the previous sections identified the key opportunities for trend management, any discussion of plan design involves many benefit choices beyond those already discussed. In developing a plan design, a sponsor should first assess its current goals and expectations for the pharmacy benefit. Typically, these expectations focus on two key elements: the growth in expenditures, or drug trend, and the potential for member dissatisfaction. As we have examined plan sponsor information, some distinctive pharmacy benefit approaches have emerged (Exhibit 42).

**General Approaches to Pharmacy Benefit Management**

## PHARMACY BENEFIT GUIDE

Exhibit 40

## PMPM Plan Cost With Pharmacy Benefit

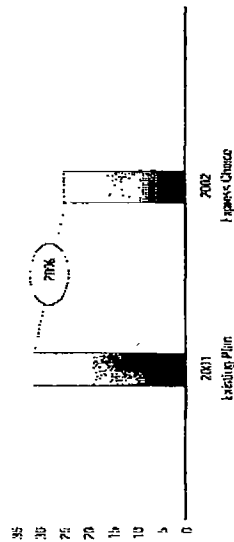
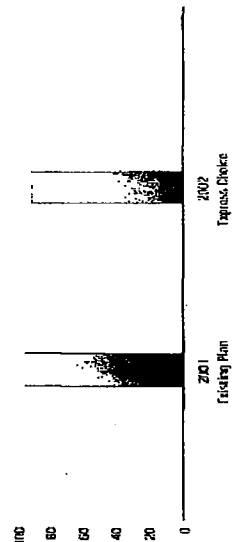


Exhibit 41

## Member Satisfaction With Pharmacy Benefit



## Express Choice: NEW LEARNINGS

A healthcare system plan sponsor realized it could no longer afford the rich pharmacy benefit provided for its 140,000 participants. It needed to begin introducing more aggressive plan-design options to manage pharmacy expenses, but it was concerned that tighter benefit management would increase member dissatisfaction. Express Choice was chosen to accomplish the plan's goals of cost management while maintaining both quality benefits and member satisfaction.

In the first year of Express Choice (2002), the client continued offering its existing benefit, while adding two more aggressive benefits that better managed pharmacy spending trend (Exhibit 39). By coupling each plan with a member premium or a monthly payroll deduction, the plan gave members an incentive to select the more aggressive options. Over time, the client phased out the existing benefit and continued to introduce more aggressive benefits. By allowing employees to choose the benefit best suited to their individual needs, the plan kept employees involved and empowered in benefit decisions.

Exhibit 39

## Pharmacy Benefits Offered Under Express Choice in the First Year

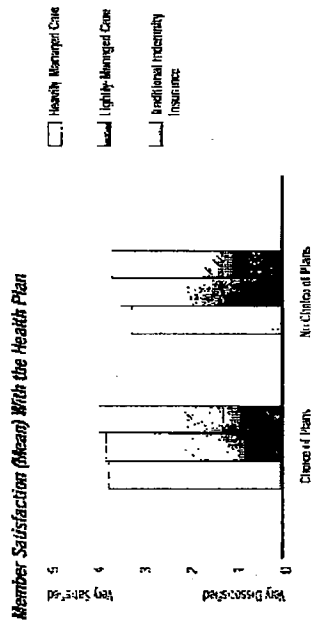
	Existing Benefit	Additional Benefit #1	Additional Benefit #2
Copayments*	\$5/\$10/\$25	\$10/\$20/\$35	\$15/\$30/\$45
Premium	\$5	\$	None
Formulary	Broader	Broader	Narrower

\*generics/formulary brands/nonformulary brands

Using Express Choice, the client was able to reduce its pharmacy expenses substantially while maintaining member satisfaction. In the first year of Express Choice, the client reduced its PMPM pharmacy cost by 70% compared to the previous year (Exhibit 40). Even with this change, member satisfaction with the pharmacy benefit continued to remain high (Exhibit 41).



## PHARMACY BENEFIT GUIDE



Offering a consumer centered prescription benefit plan allows members choices about coverage. The success of these options requires that consumers have some financial responsibility for their decisions and that they have enough information and confidence to make those decisions. To help members in their decision-making process, Express Choice is supported by an interactive, online tool during open enrollment. This tool presents the plan choices in a personalized way that demonstrates how each plan affects the member's out-of-pocket costs. When applicable, it also shows members how they can get the most from their benefit dollars by using generics and mail service. Plan sponsors implementing Express Choice have demonstrated consistent and very significant drug savings while retaining member satisfaction, as shown in the following section, **Express Choice: NEW LEARNINGS**.

### Step 5: Consumer-Driven Plan Designs

Increasingly, plan sponsors are responding to growing consumerism by offering innovative pharmacy benefits that give consumers increased accountability through more decision-making power.<sup>39</sup> Consistent with other published research, Express Scripts research has found that offering members a choice of health plans increases member satisfaction even among those who choose heavily-managed plans (Exhibit 38). This finding is the basis for Express Choice<sup>SM</sup>, which allows plan sponsors to offer multiple plans that let members select the one that best meets their needs. Then, throughout the plan year, members experience the effects of their own decisions regarding cost, coverage and flexibility, while the plan sponsor continues to manage drug expenditures. In other words, by providing members with options and allowing them to make personal tradeoffs, efficient use of the pharmacy benefit is encouraged, rather than imposed.

#### Is Express Choice a Defined-Contribution Approach?

Express Choice is similar to but not synonymous with defined contribution. The key distinction is that under defined contribution, the member bears the risk. With Express Choice, the plan sponsor bears the risk, and it is important to adjust for any selection patterns in the underwriting process. That said, the similarities between defined contribution and Express Choice include the ability for the consumer to make benefit choices, empowering the consumer through relevant information, and aligning member and plan sponsor incentives over the longer term.

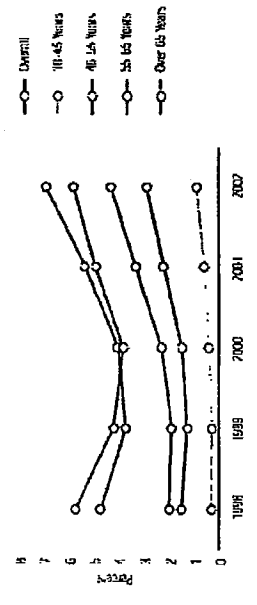
<sup>39</sup> Express Scripts Consumer Survey, November 2001. Unpublished. Administered by Knowledge Networks.

## PHARMACY BENEFIT GUIDE

**Managing Use of Erectile Dysfunction Drugs: NEW LEARNINGS**

Frequently, the use of drugs to treat erectile dysfunction is managed through a quantity limit program. The use of Viagra<sup>®</sup> increased from 1.5% of Express Scripts members in 1998 to 2.9% in 2002, an 89% increase (Exhibit 37). The fastest growing segments of users were found to be younger men, who experienced twofold in threshold increases in use. This group of potential users is the current main target of direct-to-consumer advertising. Viagra use for an identifiable underlying medical reason declined in all age groups over the five years. These factors, combined with the introduction of new erectile dysfunction products, suggest that plan sponsors can expect a considerable increase in demand for this therapy class.<sup>19</sup>

Of course, plan sponsors have additional options for managing these drugs. Some plans may decide to use a PA program not only for Viagra, but also for its recently released competitors — Cialis<sup>®</sup> and Levitra<sup>®</sup> — and for similar drugs which are expected to receive FDA approval in the next few years. Other plan sponsors may not cover them at all. Results from Express Scripts research indicate that similar savings resulted from prior authorization of Viagra and from a quantity limit of six tablets per month.<sup>20</sup>

**Exhibit 37****Proportion of Members (Males) Using Viagra 1998 to 2002**

<sup>19</sup> Delia J. Saunders, M.D., Member of United Addressed among connectivity insured adults in the United States: 1998-2002. *International Journal of Impotence Research*. (In Press)  
<sup>20</sup> Michael H. Carlini, M.D., *Pharmacy Benefit Guide*, First edition, Maryland Heights, MO: Express Scripts, Inc., February 2003.

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**QUANTITY LIMITS**

To minimize waste and stockpiling, prescriptions filled in retail pharmacies frequently are limited to a defined amount per dispensing or a specific days' supply, typically a 30-day supply per fill. Beyond the standard supply limits, additional quantity limits can be used to ensure that quantities supplied are consistent with both clinical dosing guidelines and the plan sponsor's benefit design. For example, quantity limits are sometimes used for inhalers and other drug delivery devices that contain specific numbers of doses. Another obvious use of quantity limits is for lifestyle products, such as drugs that treat erectile dysfunction.

Quantity limits can also be used to prevent billing errors. When the days' supply figure keyed in by the pharmacist is unreliable (e.g., for inhalers, which are sometimes charged by the gram and other times charged by device), a quantity limit on the units dispensed can be used to ensure that errors are caught.

Finally, quantity limits can be used to encourage dose consolidation. Manufacturers sometimes use a price purity structure — meaning that their products have little or no difference in price between the various strengths. For some cases, encouraging the use of a single unit of one strength in place of two units of half that strength is appropriate.

Drug classes for which quantity limits are frequently used include:

- Allergy Medications (oral and injectable)
- Erectile Dysfunction Agents
- Inhalers and Nasal Sprays
- Migraine Products
- Patches
- Vaginal Creams and Suppositories

When a quantity exceeding the plan sponsor's quantity limit is detected at the time of dispensing, a message indicating the quantity limitation is sent to the pharmacist. The pharmacist may either contact the physician to discuss a possible change in quantity that is consistent with the dosage guidelines or dispense the prescription until the physician can be reached. The physician may also request an override if the quantity limit is not applicable to the patient and the condition being treated.

132 express scripts

## PHARMACY BENEFIT GUIDE

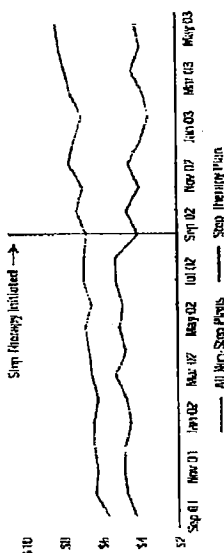
**Step Therapy: NEW LEARNINGS**

Given the relatively recent popularity of step therapy, little research reported the clinical and financial impact of step-therapy programs. To address this lack of information, Express Scripts researchers examined an employer plan sponsor that began step-therapy programs at the same time for PPIs, NSAIDs and SSRIs.<sup>26</sup>

In the first 10 months of the programs, the plan experienced cost reductions for all three drug classes (Exhibit 35). In the month following implementation, a \$0.93 PMPM decrease was seen across all three classes. In contrast, plans without step therapy averaged a \$0.10 PMPM increase across the same three therapy classes. The step-therapy process temporarily affected customer service call volume, but call volume returned to normal levels within three months of the programs' start date.

**Exhibit 35**

**PMPM Net Costs for PPIs/NSAIDs and SSRIs With and Without Step Therapy**



A survey of the members affected by the step-therapy program (1.0% of all members) found that only three in 10,000 reported calling their human resources (HR) office, while 0.2% called Express Scripts customer service (Exhibit 36). The survey also revealed that 0.05% of these members became dissatisfied with their pharmacy benefit. On average, the plan sponsor saved \$100 for every member who called Express Scripts and \$4,600 for each member who called the HR office.

**Exhibit 36**

**Step-Therapy Savings Offset Member Disruption**

Description	Savings
0.05% of members become dissatisfied	\$2,700
0.05% call HR	\$4,600/HR call
0.2% call Express Scripts	\$700/call
1.0% affected	\$140/members affected

<sup>26</sup> Unpublished Express Scripts data

## PHARMACY BENEFIT GUIDE

**How Does Step Therapy Work?**

Step therapy is administered at the pharmacy. It involves real-time checks of the member's prescription claims history for prior use of a first-line agent, as well as for previous use of the branded agents (a practice known as grandfathering). In both of these instances, a plan automatically will provide coverage for the branded agent.

Sometimes, step therapy is combined with automated PA criteria. For example, the goal of a step therapy program for the COX-2s is for patients to try a generic NSAID first. However, for patients with certain medical conditions, COX-2s may be preferred over traditional NSAIDs. By reviewing data in the prescription claim history, we can identify patients with some of those conditions and avoid the inconvenience associated with the PA claim rejection. For instance, patients who are valid candidates for COX-2s (e.g., older patients) can be identified and the step-therapy requirement can be eliminated automatically.

**How Much Does Step Therapy Save?**

Savings from step therapy programs are significant, reaching 5% of overall drug spend. It is important to understand that the amount of grandfathering decreases over time as previous users discontinue the medication. Conversely, savings increase over time because savings result from both initial prescriptions for new users and refills for patients whose prescriptions hit the program edit in previous months. The amount of time needed to reach a steady level of savings varies by therapy class. Express Scripts has studied both the economic and clinical outcomes of step therapy. Step therapy results from one client are shown in the following NEW LEARNINGS section.

COX-2 cost-effectiveness studies have been conducted to compare the costs and adverse GI outcomes of COX-2s with traditional NSAID agents. Many of these studies have concluded that COX-2s are cost-effective. However, a key assumption in the extent of co-prescribing with gastroprotective agents (GPAs), such as PPIs or H2s, to reduce the risk of GI events. All COX-2 cost-effectiveness studies either assume that patients on COX-2 therapy would not require a GPA or that their rate of GPA use would be substantially lower than with traditional NSAIDs. Because cost-effectiveness results were sensitive to the GPA rate assumption and because no empirical data to support such an assumption exist, the goal of a recently published Express Scripts study was to validate the assumption using actual practice data.

Results indicate that the GPA rate for COX-2 patients is marginally higher than the rate for traditional NSAID patients. As shown in Exhibit 34, a re-estimate of cost-effectiveness models using the GPA rates from actual practice suggests that the cost per year of life saved increased from \$18,614 to over \$100,000.<sup>b</sup>

**Exhibit 34****COX-2 Cost-Effectiveness Model, GPA Rates and Outcomes**

GPA Rate	Model	Express Scripts Data
NSAID	26%	28%
COX-2	8%	20%
Cost per Year of Life Saved	\$18,614	\$106,192

The findings from both of these studies point to the savings opportunities and provide the clinical and financial rationales for step therapy for COX-2s.

<sup>a</sup> Silverstein H, Fain G, Gekhtman B, et al. Gastrointestinal toxicity with celecoxib vs nonsteroidal anti-inflammatory drugs for osteoarthritis and rheumatoid arthritis: the CLASS study: a randomized controlled trial. *Journal of the American Medical Association*. 2002;288:1747-1755.

<sup>b</sup> Cox ER, McNeil JJ, Wager D. Verification of a decision analytic model assumption using real-world practice data: implications for the cost effectiveness of cyclo-oxygenase 2 inhibitors. (COX-2s). *The American Journal of Managed Care*. 2003;9(17):785-794.

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## Step Therapy for COX-2s: NEW LEARNINGS

## PROFILE OF NEW COX-2 USERS

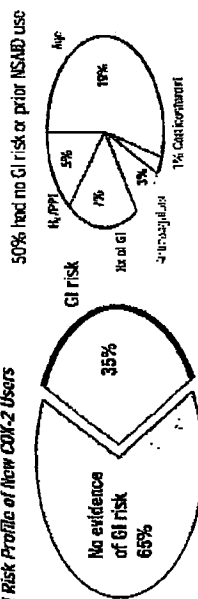
Why implement step therapy for COX-2s? Studies published by Express Scripts researchers in 2003 provide the answer.<sup>24</sup> From 1999 to 2001, the PMPY costs for the therapy class of anti-inflammatory drugs grew by 50%. This growth was attributed to the introduction of the newer, more expensive COX-2-selective agents, whose combined market share grew to 47% in 2001.

To help clients better understand how these agents are being used in real-world practice, and to determine whether COX-2s are being reserved for members at risk for adverse GI events, medical and pharmacy claims data were studied to evaluate the use of COX-2s within a large managed care organization.

The profile of COX-2 use was predominantly short-term for a variety of musculoskeletal conditions. Our results indicate that 50% of new COX-2 users were not at risk for GI events, and they had not tried a lower-cost non-selective NSAID agent prior to beginning COX-2 therapy.

## Exhibit 33

## GI Risk Profile of New COX-2 Users



Express Scripts research has also identified other opportunities to encourage cost-effective prescribing among patients on long-term COX-2 therapy. For example, when surveyed about their use of OTC agents, 45% of patients taking COX-2 therapy on a long-term basis also indicated they were using aspirin regularly for cardioprotection. Findings from the CLASS study<sup>25</sup> suggest that concomitant aspirin use negates the GI benefit of COX-2s, calling into question one of the fundamental rationales for prescribing this expensive therapy class -- the minimization of serious GI bleeding.

<sup>24</sup> Cui LR, McNeil LR, Meyer D. Verification of a decision analytic model assessing the use of world practice data: implications for the cost effectiveness of cyclooxygenase-2 inhibitors (COX-2s). *The American Journal of Managed Care*. 2003;9(12):765-768.

<sup>25</sup> Cui LR, McNeil LR, Meyer D, Beltrami A, Meyer D. Prescribing COX-2s for patients new to cyclooxygenase-2 inhibitors: a decision analytic model. *The American Journal of Managed Care*. 2003;9(12):765-768.

## Clinical Evidence Supporting Step Therapy

The clinical literature often provides head-to-head comparisons of safety and efficacy for proposed first- and second-line therapies. Two examples are antidepressants and non-steroidal anti-inflammatory drugs (NSAIDs). In the case of antidepressants, a pivotal study of the selective serotonin reuptake inhibitors (SSRIs), published in the Dec. 19, 2001, issue of the *Journal of the American Medical Association*, found no difference in patient outcomes based on which SSRI the patient was initially prescribed.<sup>26</sup> Although about 20% of patients did switch SSRIs during the trial in an effort to optimize effectiveness, no significant differences were seen in clinical effectiveness or in the rate of switching across the SSRIs originally prescribed. In addition, individual patient characteristics were not reliable predictors of better or worse response to a particular SSRI. Accordingly, the study provided strong support for step therapy programs that require a trial of fluoxetine before stepping up to the more expensive branded SSRIs.

In the NSAID class, numerous studies have shown that, at equipotent doses, COX-2 inhibitors (COX-2s) and first-line non-selective or traditional NSAIDs are equally effective in the management of acute pain and other conditions associated with pain.<sup>27</sup> While COX-2s have been shown to reduce the risk of serious gastrointestinal (GI) adverse events significantly, in the much higher cost of these agents does not offset the added benefit in the general population.<sup>28,29</sup> COX-2 therapy has been found cost-effective for patients at risk for NSAID-related GI problems (i.e., older patients, those using corticosteroids or warfarin concomitantly with NSAIDs, patients who have had a prior GI event).<sup>30</sup> Express Scripts recently conducted research that examined the number of COX-2 users who would be candidates for a step-therapy program. The study methodology and findings are described in the following NEW LEARNINGS section.

<sup>26</sup> Kowatch K, West SJ, Scialoja B, et al. Similar effectiveness for paroxetine, fluoxetine, and sertraline in primary care: a randomized trial. *Journal of the American Medical Association*. 2001;286(22):2961-2965.

<sup>27</sup> Cui LR, McNeil LR, Meyer D. Verification of a decision analytic model assessing the use of world practice data: implications for the cost effectiveness of cyclooxygenase-2 inhibitors (COX-2s). *The American Journal of Managed Care*. 2003;9(12):765-768.

<sup>28</sup> Subramanian P, Finkelstein L, et al. Gastrointestinal toxicity with celecoxib vs nonsteroidal anti-inflammatory drugs for osteoarthritis and rheumatoid arthritis: the CLASS study: a randomized controlled trial. *Journal of the American Medical Association*. 2000;284(12):1297-1305.

<sup>29</sup> Bombardier C, Laine C, Beltrami A, et al. Comparison of upper gastrointestinal toxicity of rofecoxib and naproxen in patients with rheumatoid arthritis. *New England Journal of Medicine*. 2000;342:1500-1508.

<sup>30</sup> Spiegel BM, Bergman L, Dolan CS, Graine M. The cost effectiveness of cyclooxygenase-2 selective inhibitors in the management of chronic arthritis. *Annals of Internal Medicine*. 2003;139(10):781-786.

<sup>31</sup> Spiegel BM, Bergman L, Dolan CS, Graine M. The cost effectiveness of cyclooxygenase-2 selective inhibitors in the management of chronic arthritis. *Annals of Internal Medicine*. 2003;139(10):781-786.

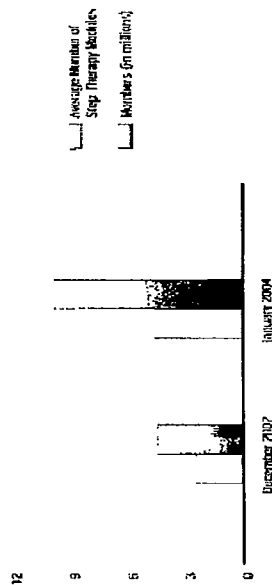
## PHARMACY BENEFIT GUIDE

## STEP THERAPY

## What Is Step Therapy?

Step therapy is designed to encourage use of therapeutically-equivalent, lower-cost alternatives (first line therapy) before stepping up to more expensive therapy (second-line therapy). In 2002, an estimated 28% of employers surveyed had implemented step therapy for one or more therapy classes.<sup>24</sup> From December 2002 to January 2004, the number of Express Scripts members enrolled in a plan with at least one step-therapy program grew from 4.5 million to 9.8 million. Additionally, the average number of step-therapy modules per client utilizing step-therapy programs increased from 2.5 to 4.6 modules (Exhibit 31).

Members Enrolled in Plans With Step Therapy



The growth in pharmaceutical step-therapy programs is fueled by the growing number of therapeutically-equivalent treatment alternatives available for many health conditions. However, it is important to point out that having a less expensive generic product in the therapy class does not automatically make a drug category an appropriate candidate for step therapy. The first-line drug must be therapeutically equivalent to the second-line drug. Therapy classes and subclasses that are candidates for a step-therapy program are shown in Exhibit 32.

<sup>24</sup> The Prescription Drug Benefit Cost and Plan Design Survey Report, provided by Ibsa, 2003 Edition. Abingdon, MA: Wellman Publishing, Inc. 2003.

## Step-Therapy Opportunities

Drug Class	First-Line Drug	Second-Line Drug(s)
Agents for Allergic Rhinitis	Oral NSA (e.g., levatadine)	Leukotriene pathway inhibitors
Agents for ADHD	Generic stimulant (e.g., methylphenidate)	Strattera <sup>®</sup>
Alkosterone Blockers	spironolactone	Inspira <sup>™</sup>
Antiasthmatics	albuterol	Xopenex <sup>®</sup>
Antidepressants	Generic SSRI (e.g., fluoxetine)	Brand SSRIs
Antidiabetics	metformin	Glucophage XR <sup>®</sup>
Antihypertensives	Generic ACEI (e.g., lisinopril)	Brand ACEI, ARB
Anti-inflammatory Agents	Generic NSAID (e.g., ibuprofen)	Brand NSAIDs, COX-2s
Anxiolytics	Generic benzodiazepine (e.g., diazepam)	Brand benzodiazepine
Bile Acid Sequestrants	cholestyramine colestipol oral suspension and microtized tablets	Welchol <sup>™</sup>
Cholesterol-lowering Agents	statin (e.g., lovastatin)	Zocor <sup>™</sup>
Gastrointestinals	Generic H2 (e.g., cimetidine) or generic PPI (e.g., omeprazole)	Brand PPIs
Topical Immunomodulators	Generic corticosteroid (e.g., augmented betamethasone dipropionate)	Lidell <sup>™</sup> Protopic <sup>®</sup>

## Abbreviations

ACEI	Angiotensin converting enzyme inhibitor
ADHD	Attention deficit/hyperactivity disorder
ARB	Angiotensin 2 receptor blocker
COX-2	Cyclo-oxygenase-2 inhibitor
H2	Histamine 2 receptor blocker
NSAID	Non-steroidal anti-inflammatory drug
PPI	Proton pump inhibitor
SSRI	Selective serotonin reuptake inhibitor



## PHARMACY BENEFIT GUIDE

## PRIOR AUTHORIZATION

With a prior authorization (PA) program, approval from the plan sponsor (or its agent) is required before the drug is covered. Typically, approval is contingent upon one of the following:

- Documentation of a specific diagnosis (e.g., hypotuitarism for growth hormone)
- Other relevant clinical characteristics (e.g., risk factors) that makes the drug medically necessary
- Participation in a wellness program (e.g., educational and exercise classes for anti-obesity medications)

PA is often used to manage the dispensing of drugs that are relatively expensive and that also may have a significant potential for inappropriate use. Simply being high-cost is not sufficient reason to place a drug on PA. However, PA can be used to limit coverage of drugs to those patients for whom there is no appropriate alternative, while disallowing coverage for patients for whom other, less expensive treatments are suitable. Clinical reasons may also affect a drug's PA status. For example, a drug that requires close monitoring because of potentially serious side effects could be placed on PA to facilitate the monitoring.

The cost-effectiveness of PA for prescription drugs has been questioned.<sup>29</sup> For such programs to be cost effective, the cost of the program to the plan sponsor must be less than the resulting drug savings. Express Scripts research found that PA provides significant plan sponsor savings amounting to about 1% of total drug spend when used for the classes of medications listed in Exhibit 30.

## Drugs Commonly Placed on Prior Authorization

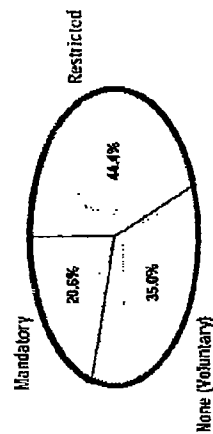
Alpha-1 Antitrypsin Replacement	Injectable Osteoporosis Treatment
Antifungals	Prescription Oral Smoking Cessation Products
Bocutrium Inair	Red Blood Cell Enhancers
Diabetic Foot Ulcer Medication	Topical Trinitrolin & Isotretinoin
Growth Hormone	
Injectable Asthma Treatment	

<sup>29</sup> Hansmann D. What is the real cost of prior authorization? *Drug Benefit Insights*. 2006;17(10):22-24.

## Will Consumers Select Generics?

A recent survey found that the majority of consumers believe that generics are just as effective as their brand counterparts.<sup>27</sup> In addition, many consumers who do not believe generics are as good are willing to pay more for the brand. Thus, a generic policy represents an important trend tool, and research shows that it produces no member dissatisfaction. (See the previous NEW LEARNINGS section, Satisfaction With the Pharmacy Benefit, for details.)

Type of Generic Policy: Express Scripts Clients Fourth Quarter 2003



<sup>27</sup> Express Scripts Consumer Survey November 2003. Unpublished. Administered by Knowledge Networks.

## PHARMACY BENEFIT GUIDE

**Reverse Copayment**

Similar to reference pricing, a reverse copayment fixes a set contribution from the plan sponsor for each agent in a given therapy class. All agents in the class are reimbursed at the same cost to the plan, and members are responsible for the remainder of the total drug cost.

**High Performance Formulary**

Express Scripts believes that it is possible to get the same or even higher savings as reference pricing by using our high performance formulary (HPF). The HPF is a generic-based formulary that includes only those brand drugs clinically recommended by the Express Scripts Pharmacy and Therapeutics (P & T) Committee. When implemented as a three-tier formulary with a 100% copayment for nonformulary products or as a two-tier closed formulary, the HPF can save clients as much as 40% of their drug spend.

Unlike reference pricing or reverse copayments, the HPF allows plan sponsors to:

- Provide a traditional, easily-understood copayment structure for formulary products across all classes
- Avoid cost-shifting to members
- Continue to receive rebates (i.e., volume discounts) on branded agents that are included on the formulary
- Help members predict their costs, understand when it is important to talk with their physicians about lower-cost alternatives and understand the exact out of pocket savings the change will represent

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**Step 4: Point-of-Service Programs**

Generally, point-of-service (POS) programs are the most effective and most efficient ways to optimize prescription utilization because they are based on financial incentives, they occur at the time the prescription is dispensed and they generally do not require additional resources to implement. Accordingly, plan sponsors should ensure that they have taken advantage of all POS programs before implementing retrospective programs. The following section examines key POS programs, including:

- Generic Policy
- Prior Authorization
- Step Therapy
- Quantity Limits

**GENERIC POLICY**

For a generic drug to receive an "A" rating from the U.S. Food and Drug Administration (FDA), it must have the same efficacy, safety and purity profile as its brand-name equivalent. Given the typical cost difference of \$47 between multi-source brands (i.e., brands with a generic equivalent available) and their generic counterparts, promoting the use of generics represents an important brand-management tool.

Generics Preferred is the name for Express Scripts mandatory generic policy, which requires a member to pay the difference in price between a brand and generic if the member chooses to get a brand medication when an FDA-approved generic equivalent is available. The rationale behind this approach is that the generic is an FDA approved equivalent to the brand, and thus there is no clinical reason for the plan sponsor to pay for the more expensive brand medication. Clients can also implement a restricted generic policy (Generics Preferred Physician's Choice) in which the member does not have to pay the price difference between the brand and generic when the physician issues a dispense as written (DAW) order.

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**Reference Pricing**

Reference pricing (also known as therapeutic MAC) is a benefit strategy intended to manage a plan sponsor's pharmaceutical costs by paying only an amount equal to the lowest priced drug of equal efficacy in the class. This technique, which began outside the United States, has demonstrated success in nationally-sponsored healthcare systems where this strategy can have a dramatic influence on the pricing behavior of pharmaceutical manufacturers, as well as on the prescribing patterns of physicians.

That said, reference pricing is not an optimal plan design for plan sponsors in the United States for several reasons:

- In some drug classes, no one drug will meet the clinical needs for all uses of drugs in the class. In these cases, a reference based price for one drug will not work, and plan sponsors are forced to administer a duplicate benefit design for those classes, making the plan difficult to operationalize and adding complexity for the member.
- Due to the decentralization of the U.S. healthcare system, the use of reference pricing by any given plan sponsor (even large ones) is very unlikely to alter the pricing behavior of pharmaceutical manufacturers, thereby producing limited savings beyond cost-shifting to members.
- Reference-based pricing makes it difficult if not impossible for patients to know what they will pay for prescriptions. Each drug class and each drug within the class may have a different price.
- Reference pricing limits the ability to negotiate volume discounts, which lower the cost of prescriptions, on behalf of the plan sponsor.
- Without accompanying tactics for shifting market share, costs simply move to the members.
- As a significant departure from traditional plans, this design requires a substantial education campaign.

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**EMERGING PLAN DESIGNS**

As plan sponsors continue to explore value-based solutions for managing drug trend, several plan designs are gaining increased attention. Among them are four tier designs, reference pricing and reverse copayments.

**Four-Tier Design**

Four-tier plans can be structured in various ways, both in terms of which drugs are placed on the fourth tier (e.g., nonformulary or high-cost medications) and the cost-sharing structure (e.g., copayment or coinsurance). For example, in one four-tier design, members could bear a smaller financial responsibility for classes of prescription drugs that are deemed to be of greatest value for extending life (Exhibit 28). Examples of such classes include medications for diabetes (e.g., insulin), asthma (e.g., inhaled corticosteroids) and cardiovascular conditions (e.g., beta blockers and ACE inhibitors). Member confusion about copayments is the biggest disadvantage of this plan design.

**Four-Tier Design****Selected Therapy Classes**

<b>Tier 3</b> Nonformulary Brands: \$30	<b>Tier 2</b> Formulary Brands: \$15	<b>Tier 1</b> Generics: \$5
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**All Other Therapy Classes**

<b>Tier 4</b> Nonformulary Brands: \$50 or 100% copayment	<b>Tier 3</b> Formulary Brands: \$30	<b>Tier 1</b> Generics: \$5
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## PHARMACY BENEFIT GUIDE

## CLOSED FORMULARIES

While three-tier copayments represent the most popular cost-sharing structure among Express Scripts clients, closing formularies represents a more aggressive type of traditional plan design that is making a comeback. With the number of generic drugs now available in the major therapy classes, closing a formulary may lead to significant savings for the client.

In a closed formulary, nonformulary drugs are not covered. Members who choose to take a nonformulary medication may receive a claim rejection at the pharmacy, or they may pay 100% of the discounted cost for the medication (i.e., the medication is dispensed at the standard network discount rate, not the higher Usual and Customary fee). However, members can always ask their doctors to request a prior authorization to receive coverage for the nonformulary drug when medically necessary.

The popularity of closed formularies has fluctuated over the years, showing considerable uptake in the early 1990s, but being supplanted by the three-tier design in more recent years. The obvious advantage of a closed formulary, as documented in an Express Scripts study published in *Inquiry* in 1999, is that it provides substantial savings for a plan sponsor.<sup>21</sup> The potential disadvantage with a closed formulary, however, is that it may produce resistance from members and providers. Clients that have the ability to inform their members, physicians and pharmacies proactively about the formulary can manage much of the potential disruption. Accordingly, closed formularies are most frequently adopted by large health plans with a large market penetration and greater influence with physicians.

<sup>21</sup> Michael B. Henderson R. The effect of a closed formulary on prescription drug use and costs. *Inquiry*. Winter 1999;20(3):461-481.

The most significant step a plan sponsor can take to promote the use of generics is to adopt a high-performance formulary (HPF) – a closed formulary consisting of generics and lower-cost brands. As more branded products go off patent, it is possible to increase the use of generics through formulary design. Branded products covered in the HPF are either in therapy classes without a clinically-equivalent generic or they are needed for clinical reasons.

The HPF can provide clients with immediate savings of as much as 40% off their current drug spend. Additionally, with brand-name drugs that will lose patent protection by 2008 representing over \$30 billion in drug spend, this formulary positions clients to take immediate advantage of newly-introduced generics as they are approved.

Express Scripts suggests that clients implement an aggressive, proactive communications strategy to educate members, physicians and pharmacies about the HPF and how to take advantage of it. The educational campaign should center on protecting member benefits, eliminating waste from the system without affecting health status and making stakeholders aware of equivalent medications that are covered.

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**OTC Claritin®: NEW LEARNINGS**

When all forms and strengths of Claritin, a prescription non-sedating antihistamine (NSA), became available for sale as over the counter (OTC) products in December 2002, plan sponsors had a number of trend-management options available for OTC Claritin as well as for the NSA products that remained prescription-only. All benefit designs had similar increases in the rate of spend for Singulair® and Flonase®, non-NSA anti-allergy prescription drugs (Exhibit 27). However, plans that moved prescription NSAs to a third tier and excluded OTC Claritin from their benefits experienced, on average, a 17% PMPM decrease in spend for all anti-allergy drugs, while other benefit designs saw decreases of only 1% to 10%.<sup>20</sup>

The study findings demonstrate:

- Moving prescription NSAs to a third tier resulted in the greatest savings for plans through greater member cost-sharing and decreased utilization.
- Plans should not cover OTC Claritin without step therapy unless OTC drugs are a standard part of the benefit.
- Inexpensive of plan design choices for NSAs, step therapy should be considered for Singulair given the more than 30% increase in Singulair costs for all plans since 2002, when Singulair received an indication for allergic rhinitis.

**Exhibit 27**

**Change in Prescription (Rx) Anti-Allergy Drug Spend and Use  
January to June 2002 Versus January to June 2003**

Benefit Type (# Plans)	MEAN PMPM Rx CHANGE		MEAN NET PMPM \$ CHANGE		
	Rx NSA	Rx NSA	Rx NSA	Singulair Flonase	Total Anti-Allergy
Covered OTC Without Step Therapy (40)	-8.50%	11.40%	30.30%	19.40%	1.40%
Did Nothing (1732)	-22.80%	-23.70%	33.40%	21.00%	-9.60%
Placed NSAs on Third Tier (7)	-31.80%	-32.30%	33.60%	19.70%	-17.20%

<sup>20</sup> Deane L. Henderson, M.D., Mofatt, D.R. "Financial Impact of Benefit Design Choices for Non-Sedating Antihistamines Express Scripts, Inc. Available at: [http://www.express-scripts.com/other/news\\_views/analyses\\_research/timeline\\_publications.html](http://www.express-scripts.com/other/news_views/analyses_research/timeline_publications.html). Accessed February 21, 2006.

## PHARMACY BENEFIT GUIDE

**Three-Tier Benefit Designs: NEW LEARNINGS**

In summary, the evidence indicates that three-tier copayment structures:

- Provide greater trend-management than two-tier copayments
- Achieve drug cost-savings through reduced use of tier three medications, greater cost-sharing by members and greater rebates for tier two medications
- Are both clinically and financially responsible, as research indicates that a three-tier copayment produces no unintended consequences

In the Dec. 4, 2003, issue of the *New England Journal of Medicine*, researchers reported on the impact of three-tier benefit designs on prescription utilization for three therapy classes used to treat chronic illnesses. In evaluating two employer groups that implemented three-tier designs in 2000, the researchers found that after moving to a three-tier design, members in one group were more likely to discontinue use of their medications than those in the comparison group. However, in a second employer group, they found no significant differences in rates of discontinuation for any of the three therapy classes after moving to a three-tier design.<sup>11</sup>

Why the contrasting results? The difference in outcomes likely was due to the way that three-tier designs were implemented. The first employer group moved radically from a single-copayment design for brands and generics to a three-tier design, while the second employer group moved incrementally from a two-tier to a three-tier plan design. Express Scripts discourages its clients from moving directly to a three-tier design from a single-copayment design, particularly in the absence of extensive member education.

Another contributing factor for the differences could be related to the different worker profiles of the two employer groups. The first group was a large firm with mostly hourly workers, suggesting lower-income workers; while the second group, also a large firm, employed mostly salaried workers.

Furthermore, the study did not address whether implementation of a three-tier plan design affected other medical use. Examining both pharmacy and medical data, Express Scripts research found that moving gradually from a two-tier to a three-tier design not only slowed the drug cost trend but also had no unintended consequences in other use of other medical care services or rates of medication continuation. The original study, published in the journal *Medical Care* in 2001, followed members for 12 months.<sup>12</sup> The most recently published Express Scripts study found the same results after following members for a full 30 months post-three-tier implementation.<sup>13</sup>

**Implications**

- Three-tier benefit designs can slow drug cost trends without unintended consequences.
- Three-tier benefit designs should be implemented after taking into consideration current plan design and member characteristics, and should be accompanied by appropriate member education.

<sup>11</sup> Hayskamp JA, Boverice PA, Fisman ME, Upstein KS, McGowan KA, Frank RG. The Effect of Income-Based Formulary on Prescription Drug Utilization and Spending. *New England Journal of Medicine*. 2003; 349:2372-2379.

<sup>12</sup> Fisman ME, Boverice PA, Hayskamp JA, Upstein KS, McGowan KA, Frank RG. The Effect of Income-Based Formulary on Prescription Drug Utilization and Spending. *New England Journal of Medicine*. 2001; 345:1203-1209.

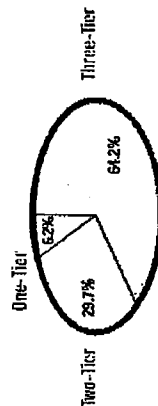
<sup>13</sup> Express Scripts. 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## PHARMACY BENEFIT GUIDE

**TWO-TIER VERSUS THREE-TIER COPAYMENTS**

Once the choice of a copayment or coinsurance structure has been made, the next decision is the number of tiers to employ, typically two or three. The three-tiered copayment structure provides an incentive for members to use generics and formulary brands because their out-of-pocket cost will be reduced significantly. The popularity of three-tier copayments has grown substantially in recent years because they offer comparable savings, greater member choice and ease of administration compared to closed formularies.

Formulary Structure: Express Scripts Clients Fourth Quarter 2003

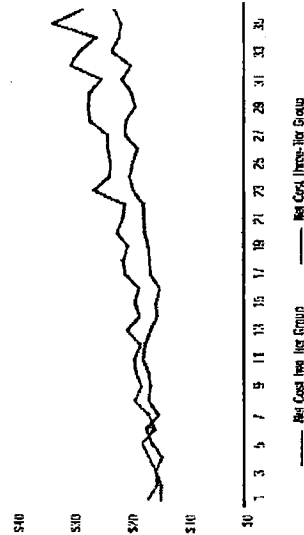


What Is a Three-Tier Copayment?

Tier 3	Nonformulary Brands
\$30-\$40	
Tier 2	Formulary Brands
\$15-\$25	
Tier 1	Generics
\$5-\$10	

Despite its advantages, some have questioned whether a three tier copayment structure is effective at managing trend and whether it produces unintended consequences, such as more office visits or higher medication noncompliance. To address these questions, Express Scripts examined the impact of a three-tier program on prescription utilization and expenditures, medication compliance and utilization of other medical services. As discussed in the following Three Tier Benefit Design: NEW LEARNINGS section, the study followed members over a three year period, finding no negative clinical impact from moving to a three-tier plan (Exhibit 26).

Payer Cost Net of Copayment per Member



In 2003, three-tier copayments were used in a unique way by some plan sponsors as a strategy for managing the non-sedating antihistamines (NSAs). Several plan sponsors moved all NSAs to the third tier to encourage members to use OTC Claritin®. As discussed in the following text, these plan sponsors experienced a 32% decrease in drug spend for NSAs. This strategy will become increasingly common not only as other plan sponsors learn from the experience of these plans, but also as more medications become available in non prescription forms.

## PHARMACY BENEFIT GUIDE

## Implications

- Plan sponsors can implement a generic policy without concern for member dissatisfaction, consistent with research showing that members believe generics are safe and effective.
- Coinurance creates dissatisfaction, likely due to unpredictable out-of-pocket payments.
- Educating members about copayment increases and about alternatives when denied coverage can mitigate negative effects on satisfaction.

In summary, Express Scripts research indicates that coinsurance provides no advantage over copayment designs in terms of encouraging the use of less expensive medications. However, coinsurance ensures that member cost-sharing, as a percentage of total drug costs, automatically keeps pace with rising drug costs, making it unnecessary to adjust copayment levels every few years. Its key disadvantage is that members cannot determine their out-of-pocket cost before the medication is dispensed ... a likely reason for lower member satisfaction with coinsurance.

## Satisfaction With the Pharmacy Benefit: NEW LEARNINGS

While the pharmacy benefit is one of the most frequently used healthcare benefits, historically little has been known about member satisfaction with this benefit and how benefit-design factors affect satisfaction. To fill this gap, Express Scripts researchers surveyed a random sample of over 14,000 Express Scripts members who had a recent prescription drug claim.<sup>14</sup>

This study found that a substantial majority (64%) of the respondents reported that they were satisfied with their pharmacy benefit — even more so than with their medical plans (Exhibit 23). In a statistical model that controlled for gender, age, income and member health status, neither a mandatory generic policy nor a three-tier design was found to affect satisfaction with the pharmacy benefit.

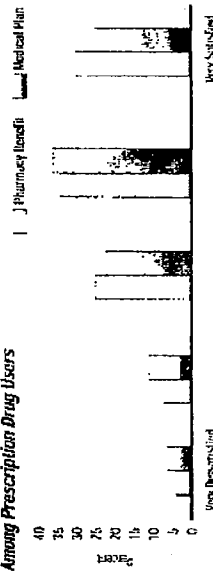
However, predictors of dissatisfaction with the pharmacy benefit were:

- Coinurance
- Copayment increase in the past year
- Drug coverage denial in the past year
- Large health insurance premium
- Enrollment in heavy managed care

## Exhibit 23

## Satisfaction With the Pharmacy Benefit and the Medical Plan

## Among Prescription Drug Users



<sup>14</sup> Mathur et al. Review SM: Predictors of Satisfaction of Health Plan Members with Prescription Drug Benefits. *American Journal of Health-System Pharmacy*. (In Press)

## PHARMACY BENEFIT GUIDE

## COINSURANCE

A limitation of any fixed-dollar copayment structure is that it does not automatically keep pace with drug price increases. Thus, member cost-sharing is reduced over time. In contrast, coinsurance automatically keeps pace with rising drug prices.

A disadvantage of coinsurance is that members cannot readily determine the price of the medication before it is dispensed at the pharmacy. In other words, the member's out of pocket cost for each prescription is unpredictable. This uncertainty makes coinsurance less appealing to members. Express Scripts research has found less satisfaction with the pharmacy benefit among members with coinsurance.<sup>14</sup> The study findings are discussed in detail on the following pages.

However, some have questioned whether the use of coinsurance may grow as plan sponsors search for trend-management strategies. In particular, some in the industry have asked whether coinsurance is more effective than dollar copayments at increasing the use of generics and lower-cost brands. To this end, Express Scripts examined the effectiveness of coinsurance in encouraging the use of lower-cost alternatives, such as generics, and found no difference in the likelihood of using less expensive brands or generics among coinsurance versus copayment plans.<sup>15</sup>

Given that members pay more for more expensive drugs with coinsurance, why doesn't coinsurance result in greater use of generics and less expensive brands? The answer likely stems from the realities of the prescribing process. Frequently, at the time of writing a prescription, a physician is unaware of the medication's cost. Accordingly, a patient typically does not know the cost of the medication until he or she goes to the pharmacy to have the prescription filled. Once at the pharmacy, it is unlikely that the patient will contact the doctor to ask for a less expensive medication. Thus, coinsurance's ineffectiveness in promoting greater use of less expensive brands and generics may reflect physicians' and patients' lack of awareness of medication costs.

<sup>14</sup> Michael B. Liodonum, "From R. Pharmacy Benefit Goals First Edition, Maryland Heights, MO: Express Scripts, Inc. February 2003.  
<sup>15</sup> Michael B. Liodonum, "From R. Pharmacy Benefit Goals First Edition, Maryland Heights, MO: Express Scripts, Inc. February 2003.

### Step 3: A Cost-Sharing Structure That Meets the Goals and Needs of the Plan Sponsor

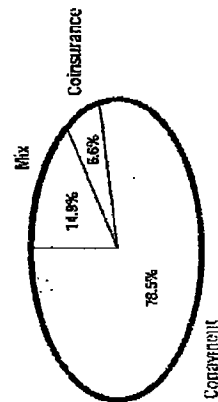
One of the first steps in developing a plan design is determining what cost-sharing structure to use. Traditional options include a copayment or coinsurance design with a single tier, two tiers or three tiers. Copayments, in general, are easily understood by members. However, single-tier (flat dollar) copayments, which set the same copayment amount regardless of drug type, do not provide incentives for members to use generics. Multi-tiered copayments, which have a lower copayment amount for generics and a higher copayment amount for brands, provide members with a financial incentive to use generics.

Copayments are fixed dollar amounts that members pay for each prescription. Plans can either have a single copayment regardless of the type of drug or use a tiered design that allows for different copayment amounts for different types of drugs (e.g., generics and brands).

Coinsurance, or percentage copayment, specifies the percentage of the prescription cost that the member pays for each prescription (e.g., 20%). The coinsurance percentage is often the same for all drugs, but it can vary for brands and generics.

Deductibles require a member to pay the entire prescription drug costs until a specified dollar amount has been paid out of pocket for each benefit period. After the deductible has been met, the member pays the standard copayment (or coinsurance rate) for each medication thereafter during that benefit period. Due in part to the relatively high potential for member confusion, very few plan sponsors use deductibles.

Cost-Sharing Structure: Express Scripts Clients Fourth Quarter 2003





## PHARMACY BENEFIT GUIDE

**Step 2: Guiding Principles for Plan Design**

As discussed in the previous section, formularies are the cornerstone of pharmacy benefit design. Before discussing additional steps in plan design development, we review the four key principles that should guide plan design:

- Manage drug trend while promoting appropriate drug use.
- Assign cost-sharing amounts that set member financial responsibility appropriately.
- Provide a member-friendly benefit in terms of communication and information accessibility.
- Develop the plan design with a three-year time horizon.

**MANAGE DRUG TREND WHILE PROMOTING APPROPRIATE DRUG USE**

As emphasized throughout this Report, the goal of pharmacy benefit management is not merely to control drug costs. Rather, the goal is to optimize drug expenditures, which requires a combination of drug cost management and clinical programs to encourage appropriate use of necessary medications. Express Scripts offers numerous programs (e.g., drug utilization review) that encourage appropriate drug utilization.

**ASSIGN COST-SHARING AMOUNTS THAT SET MEMBER FINANCIAL RESPONSIBILITY APPROPRIATELY**

Members who view prescription drugs as a nearly-free good to which they are entitled have little or no incentive for prudent consumption. By making members financially responsible for a greater part of the cost of the medications they use, plan sponsors can sensitize members to true drug costs. Express Scripts recommends that plan sponsors set the overall member financial contribution between 20% and 35%. However, clients should consider annual caps on member payments (i.e., member stop-loss) to protect the sickest patients from very high out-of-pocket spending.

**PROVIDE A MEMBER-FRIENDLY BENEFIT IN TERMS OF COMMUNICATION AND INFORMATION ACCESSIBILITY**

Plan designs should be structured in ways that members can understand and that allow them to use the benefit with relative ease. Good communication with members includes:

- Easy-to-understand explanation of benefits
- Cost-sharing structures that are clear to members
- Timely notification about changes in plan design
- Multiple channels for the member to contact the plan pharmacy benefit manager (PBM).

**DEVELOP THE PLAN DESIGN WITH A THREE-YEAR TIME HORIZON**

Given the rapidly changing pharmaceutical marketplace, it is important that a plan sponsor take a multi-year time horizon in plan design development. Taking maximum advantage of new generic opportunities requires formulary and plan-design development in advance of the generic availability. In addition, a longer-term view of plan design helps member cost-sharing keep pace with rising drug costs, thereby avoiding large copayment increases that may produce negative member reaction.



## PHARMACY BENEFIT GUIDE

Exhibit 20

## Call Center Impact After Moving to a Three-Tier Benefit

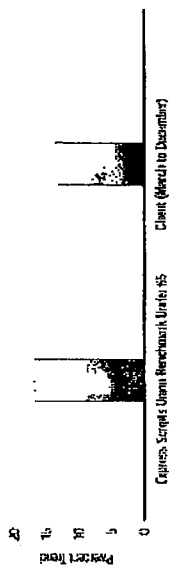
Calls Per 100,000 (Three-Tier Moving Average)



Exhibit 21

## Economic Impact After Moving to a Three-Tier Benefit

Net Cost per member Trend From 2001 to 2002



## Formulary Design Selection: NEW LEARNINGS

A union plan new to Express Scripts left intact its existing two-tier benefit design. During the following year, the plan experienced an almost 17% PMPM increase in drug costs. In addition, significant new enrollment growth further increased the need for greater cost management with minimal member disruption. To address these challenges, the plan selected a formulary with a performance list. Implemented a three-tier copayment design and educated both members and prescribers about the changes. Express Scripts researchers studied this plan to examine the call center and economic impacts of the benefit design change.

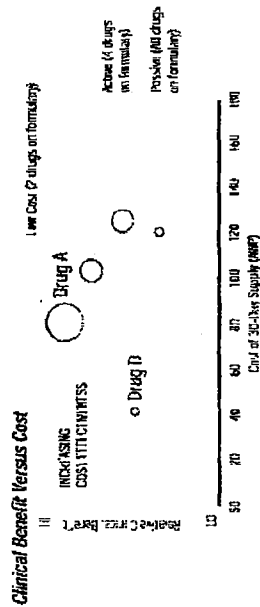
## What is a Performance List?

One benefit design that Express Scripts offers is a three-tiered formulary that may include a performance list. Performance lists limit or close only certain therapeutic subclasses, such as statins and proton pump inhibitors. As a result, members have additional financial incentives to use formulary drugs. Formularies with a performance-list option provide substantial cost savings yet minimize member disruption by affecting only the small percentage of members who might use drugs in the few affected classes.

## Key Study Findings

- Calls to the Express Scripts Call Center increased in response to the advance notification to members, but call volume quickly subsided — returning to pre-notification levels within three months (Exhibit 20).
- Annual trend for PMPM net drug costs slowed substantially to 13.5%, well below not only the client's previous annual trend of nearly 17%, but also Express Scripts 2001-2002 union benchmark of 16.8% (Exhibit 21).
- Member cost-share increased just 2 percentage points, from 12.2% to 14.2%.
- The plan's generic fill rate increased by 6 percentage points, and the use of lower-cost brands also increased, in part due to the new formulary design.

## PHARMACY BENEFIT GUIDE



## Implications

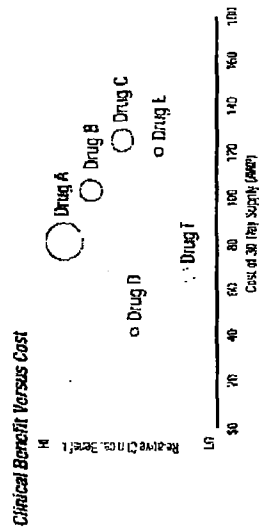
- Building a rational formulary to meet the needs of a plan sponsor's population is accomplished through a series of distinct steps. After clinical needs are met, cost is then considered, followed by analyses of market share and market dynamics.
- Express Scripts develops multiple formularies along a cost-management continuum, which allows plan sponsors to remain consistent with the twin goals of maximum cost-saving opportunities and minimal member, prescriber and dispenser disruption.
- To take full advantage of the formulary selections they have made, plan sponsors should use member and physician education programs as integral components of the benefit. Encouraging members and physicians to work together as prescribers are written helps to optimize the use of formulary drugs.

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## IS THERE ONLY ONE FORMULARY?

Since no one formulary can meet the needs of all plan sponsors, Express Scripts builds its formularies on a class-by-class basis -- positioning each therapy class along the continuum of formulary options. Using a priority approach based on the contribution of each class to total drug spend, Express Scripts consults with each plan sponsor to analyze prescription utilization patterns for its members. The result is a cost-effective formulary that meets the needs of the plan.

Exhibits 19a and 19b show how a plan can select a few, most or all drugs within a class to put on formulary. First, each drug is rated based on its relative clinical benefit and its cost.



A plan can take a passive approach and include all drugs on formulary. In an active formulary approach, a plan includes many but not all drugs on the formulary. A plan that takes a low cost approach covers the generics and lowest cost brands that meet clinical need, which would include Drugs D and A in this example.

100 express scripts

## PHARMACY BENEFIT GUIDE

2. **Consider cost.** Because agents within a therapy class usually have different average wholesale price (AWP) costs, however, accounting for cost differences allows formulary selection when drugs are equal in benefit. Lower cost drugs are selected only when their clinical benefits have been established as equal to or better than other agents in the class for a substantial group of patients. Formulary drugs may actually be higher in cost than other drugs in the class when their clinical benefits are superior to the lower cost drugs.

3. **Account for market share.** A drug's market share is important to consider for two reasons. Eliminating a widely-used drug (e.g., one with a high market share) from the formulary may create unacceptable levels of disruption among physicians, patients and pharmacies. In addition, market share considerations may have a significant impact on total costs for the therapy class. For instance, if drugs with high negotiated discounts are made nonformulary in favor of potentially lower cost agents that have little market share, costs for the therapy class may actually increase, depending on the market-share movement.

4. **Account for market dynamics over an extended timeframe.** Allowing for non-clinical drug dynamics, such as patent expirations or expected introductions of new drugs within the class over more than one year, may give formulary longer shelf lives. For example, an effective, heavily utilized but more expensive brand-name drug that will lose patent protection within a relatively short time may remain on formulary. Not only may the eventual transition to the generic equivalent be easier, the potential for member and physician disruption may be lower. Express Scripts recommends a three-year time horizon. In the therapy class review section of this Report, we explain our predictions of trends in the top 25 therapy classes over the next five years.

For a complete description of the Express Scripts formulary development process, please refer to: [http://www.express-scripts.com/outlet/company/formulary\\_development\\_whitepaper\\_2003.pdf](http://www.express-scripts.com/outlet/company/formulary_development_whitepaper_2003.pdf).

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### Step 1: Formulary Development: The Backbone of Effective Trend Management

Drug formularies form the backbone for optimizing physician prescribing and patient drug-utilization patterns. A well-designed formulary ensures that the most clinically sound and cost-effective therapy is selected for each patient. Benefit designs, such as a three-tier formulary, maximize the use of cost-effective formulary drugs. However, the selection of which drugs to promote will have the biggest impact on a plan's long-term costs.

Developing an effective formulary involves the selection of individual drugs that provide the best clinical benefit at the best cost. Using the Generic Product Identifier (GPI) codes, maintained by the Facts and Comparisons division of Wolters Kluwer Health, Inc., Express Scripts begins formulary analysis with 99 broad therapy classes, or groupings of drugs with similar chemical structures and comparable activity against specific conditions. Each of these therapy classes, such as antidepressants or antihypertensives, is further divided into subclasses (e.g., statins, fibric acid derivatives, bile acid sequestrants and nitrolic acid derivatives for antihyperlipidemic drugs) and then into individual drug products. By evaluating each drug within its therapy class for safety, efficacy, toxicity, patient convenience and overall cost, Express Scripts clinicians select the most cost-effective agents for formulary inclusion.

Express Scripts uses four analytic steps to select the formulary drugs within each therapy class:

1. **Assess clinical benefit.** Through careful analysis of published literature, drugs within each therapy class are ranked according to the relative ability of each individual agent to achieve the goal of therapy. Attributes such as side-effect profiles, potential toxicities and drug interactions are used to distinguish among the agents. The Express Scripts National Pharmacy and Therapeutics (P&T) Committee, a group of practicing physicians who are not employed by Express Scripts, makes the final decision on whether each drug should be included on the formulary. P&T Committee members do not consider cost when determining clinical benefit.

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### ***Plan Design: A Stepwise Approach To Trend Management***

Over the past 10 years, Express Scripts has conducted more than 100 research studies on how members of prescription drug plans use prescription drugs and what factors change the patterns of prescription use. This research base is used by Express Scripts to evaluate existing plans and recommend new plan designs or service offerings. From it, Express Scripts has established an evidence-based approach to manage pharmacy benefits. This section outlines both the approach recommended by Express Scripts and the research findings that underlie it.

Developing a plan design that is effective at long-term drug trend management involves five key steps:

1. **Selection of a formulary.** A range of formularies is available to meet the varying needs of plan sponsors.
2. **Incorporation of guiding principles for plan design.** Quality, equity and member understanding are three important considerations in plan design.
3. **Selection of a cost-sharing structure.** Research has provided much evidence about the economic and clinical impact of various cost-sharing and plan-design options.
4. **Selection of point-of-service programs (e.g., step therapy).** Recent research provides compelling data about the value of point-of-service programs.
5. **Incorporation of the emerging strategy: Consumer-driven plan design.** Today's consumers are interested in learning about plan decisions and the logic behind them.

*PHARMACY BENEFIT GUIDE*

4

2003

EXPRESS SCRIPTS DRUG TREND REPORT

*THERAPY CLASS REVIEW*

*Notes*

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ESI-277-00012550

## THERAPY CLASS REVIEW

## ESTROGENS

RANK 25

## COMPONENTS OF TREND

Cost per Prescription	9.1%
Initiation	19.2%
Units per Prescription	-3.7%
Brand/Generics Mix	-0.8%
Therapeutic Mix	-4.3%
Utilization	-29.6%
Prevalence	-27.1%
Intensity	-3.4%
New Drugs	0
<b>TOTAL</b>	<b>-23.2%</b>

## KEY FACTS

PMPY: \$8.41

Rx PMPY: 0.31

Prevalence of Use: 3.8%

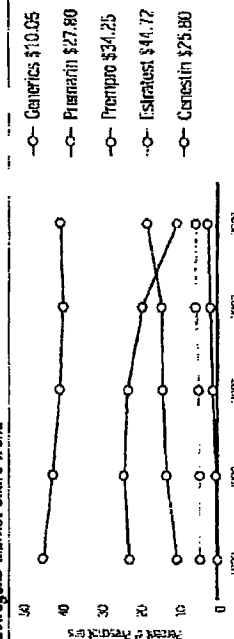
Average Cost/Rx: \$27.47

# Rx/User/Year: 8.06

Not surprisingly, drug trend for the estrogen therapy class declined significantly in 2003 as women continued to abandon hormone replacement therapy (HRT). The overall trend decrease to -23.2% was the largest among the top 25 therapy classes in 2003. It follows a -5% trend in 2002, when results of the first study questioning the safety of HRT were released. A decrease in utilization of approximately 30% was observed. It should be noted that despite the dramatic decrease in utilization, manufacturers continued to raise prices. The inflation rate of 19.2% for 2003 was not only almost three times higher than the average for all drugs, it was also the highest of the top 25 classes. At 1.1%, antineoplastics finished a distant second. Despite additional negative clinical information on the leading product, Premarin<sup>®</sup>, its average AWP cost per prescription still rose by 18.7%.

With a 40.3% market share in 2003, Premarin continued to lead the class, although the gap is closing slightly due to competition from generics. Prempro<sup>™</sup> has had the most dramatic falloff in share, dropping from 23.1% of prescriptions in 2001 to 10.5% in 2003. None of the estrogen patch products had a market share of greater than 4%, but the combined market share for all patches was approximately 15%. In addition, every estrogen patch product either maintained or grew market share in 2003.

## Estrogens Market Share Trend

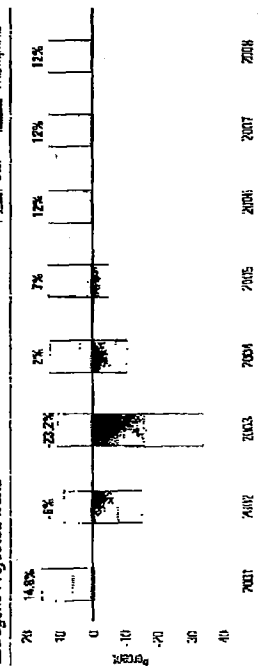


94 aspres scripts

## Looking Ahead

Unless additional studies linking estrogens to negative outcomes are published, continued utilization decreases of 30% are unlikely. However, high inflationary trends likely will continue, and utilization patterns should stabilize. We project minimal growth in the category, driven by cost increases and leveling off at about 12% by 2006.

## Estrogens Projected Trend



## PIPELINE

Brand	Generic	Manufacturer	Proposed Use	Availability
Monsieur <sup>®</sup>	estradiol, transdermal conjugated estrogens/ testosterone	Berlex Wyeth	osteoporosis prevention Menopausal symptoms/ Osteoporosis prevention	2004
Ergaster <sup>™</sup>	synthetic conjugated estrogens (plant-derived)	Barr	Menopausal symptoms	2005
Projuvia <sup>™</sup>	synthetic conjugated estrogens (plant-derived)	Durr	Prevention of endometrial hyperplasia	2006
Laseron <sup>™</sup>	estradiol conjugated estrogens/ testosterone	Ilex Wyeth	Menopausal symptoms/ Osteoporosis prevention	2007

The Women's Health Initiative (WHI) trials put a damper on future growth of the estrogen class, and as a result new products coming to market will likely have a lower profile than initially expected. Some new combination products are being studied, as are some new strengths and dosage forms of existing products. Generics to the market-leading Premarin are still being pursued, but the exact timing of possible generics is difficult to predict.

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## THERAPY CLASS REVIEW

## MACROLIDES

RANK 24

## KEY FACTS

COMPONENTS OF TREND	
Cost per Prescription	6.5%
Inflation	5.2%
Units per Prescription	0.6%
Brand/Generic Mix	0.1%
Therapeutic Mix	0.6%
Utilization	10.0%
Prevalence	8.8%
Intensity	1.1%
New Drugs	0
<b>TOTAL</b>	<b>17.1%</b>

PMPY: \$1.74

Rt PMPY: 0.20

Prevalence of Use: 13.2%

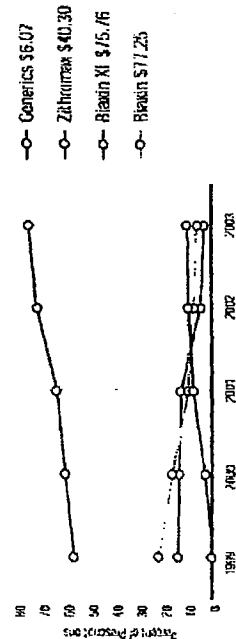
Average Cost/Rx: \$14.10

# Rx/User/Year: 1.5

During 2003, the macrolide antibiotic therapy class showed an unusual gain in overall trend, with its 17.1% increase the largest in the past four years. Growth, which had been in the low single digits, was actually negative in 2002. Utilization gains were the primary reason for the increase. Flat utilization in 2002 (0.4%) grew to 10% in 2003. Cost-per prescription trends were slightly elevated from 2002. The general increase in macrolide trend was largely due to the early start of influenza season in 2003, when many patients with flu like symptoms were apparently treated with an antibiotic instead of an antiviral.

Market share trends for the class were relatively stable in 2003. Zithromax<sup>®</sup> remained the strong market leader with over 75% of total prescriptions. The Biaxin<sup>®</sup> family of products decreased slightly in market share, from 17.6% in 2002 to 16.7% in 2003. Erythromycin products have become almost an afterthought, with the entire family of products, both brand and generic, now representing less than 7% of total macrolide prescriptions.

## Macrolides Market-Share Trend



92 express scripts

## Looking Ahead

Patent expirations will begin to play a role in this class, with the first Biaxin and Zithromax patents set to expire in 2005. It is not clear at this time when generics will actually become available, so long-term forecasting is difficult. However, with utilization trends expected to moderate in 2004 and beyond, we project annual trend increases in the range of 9% to 12%.

## Macrolides Projected Trend



PIPELINE	Generic	Manufacturer	Proposed Use	Availability
Brand	erythromycin	Pfizer	Drug-resistant malaria	2006

## PATENT EXPIRATIONS

Brand	Generic	Manufacturer	Patent Expiration
Biaxin <sup>®</sup>	clarithromycin	Abbott	May 24, 2005
Zithromax <sup>®</sup>	azithromycin	Pfizer	Nov. 1, 2005

The first member of a new class known as ketolides, Kelex<sup>®</sup>, was approved in April 2004 for the treatment of various respiratory tract infections. With a structural similarity to macrolides, it is likely to compete against existing macrolides and quinolones. An azithromycin/chloroquine combination product is also in development for the treatment of malaria.

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## THERAPY CLASS REVIEW



## STIMULANTS/ANTI-OBESITY

RANK 23

## KEY FACTS

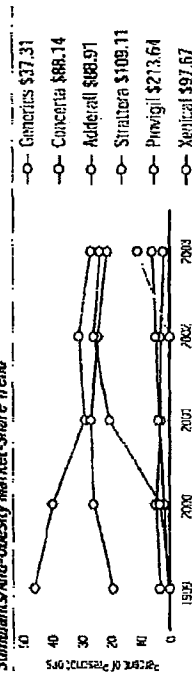
COMPONENTS OF TREND	
Cost per Prescription	17.6%
Inflation	9.0%
Units per Prescription	2.3%
Brand/Generic Mix	-4.0%
Therapeutic Mix	9.8%
Utilization	3.1%
Prevalence	-9.1%
Intensity	13.4%
New Drugs	21.0%
TOTAL	42.2%

Prevalence of Use: 1.3%  
Average Cost/Rec: \$83.84  
# Rx/User/Year: 7.99

The stimulants/anti-obesity therapy class is new to the *Drug Trend Report* in 2003 due to a remarkable 41.8% increase in trend, highest among the top 25 therapy classes. Almost half of this trend increase is due to one new drug for attention-deficit/hyperactivity disorder (ADHD), Strattera®, which was released in late 2002. Strattera is heavily marketed through DTC advertising, with specific mention of its unique, non-stimulant mechanism of action. It had the most significant impact of any new drug in 2003, accounting for \$2.43 in PMPY costs. Utilization in the class grew only 3.1%, as an increase in intensity (more people using combination therapy) was largely offset by a decrease in the prevalence of use of common drugs. Cost-per-prescription trends were higher than average due to a 9.8% increase in therapeutic mix and a 9% rise in inflation.

Generic drugs have lost significant market share in this class over the past five years, as ADHD patients are switched to newer brands. One of these newer brands is Concerta®, which is a modified-release formulation of methylphenidate. Since its introduction in 2000, Concerta has become the leading brand in the class, with a market share of 23.8% in 2003. The previous brand leader, Adderall®, has lost market share recently due to generic competition. After only one year on the market, Strattera grabbed an 11.3% share of prescriptions in the class. Among the stimulant drugs, Strattera also had the highest cost per prescription (\$109.11), which is approximately \$20 higher than other brands in the class.

## Stimulants/Anti-Obesity Market Share Trend



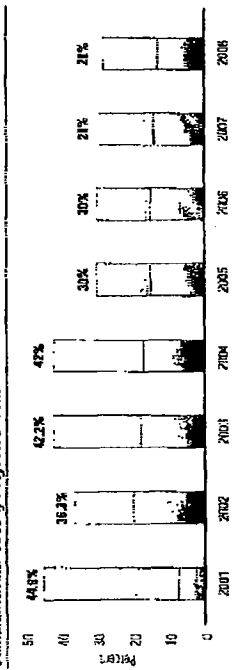
90 express scripts

## THERAPY CLASS REVIEW

## Looking Ahead

Generic market share should remain stable in the coming years as the popularity of newer branded products is offset by the increase in combination therapy. After another year of 40%-plus growth in 2004, we are forecasting growth in the 28% to 30% range between 2005 and 2008, absent active management of the class.

## Stimulants/Anti-Obesity Projected Trend



## PIPELINE

Brand	Generic	Company	Proposed Use	Availability
GW320659	ADHD	GlaxoSmithKline	ADHD	2005
Novartis	Novartis	Novartis	Novartis	2005
Novartis	Novartis	Novartis	Novartis	2005
Novartis	Novartis	Novartis	Novartis	2005
Novartis	Novartis	Novartis	Novartis	2005
Novartis	Novartis	Novartis	Novartis	2005
Novartis	Novartis	Novartis	Novartis	2005
Novartis	Novartis	Novartis	Novartis	2005
Novartis	Novartis	Novartis	Novartis	2005
Novartis	Novartis	Novartis	Novartis	2005

## PATENT EXPIRATIONS

Brand (Generic)	Generic	Manufacturer	Patent Expiration
Prologit	Prologit	Cephalon	Key patent expired
Concerta	Concerta	Celco	April 3, 2004 **
Adderall XR	Adderall XR	Shire	Oct. 11, 2004 ***
Mendia	Mendia	Abbott	Dec. 11, 2004

\*Court hearing January 2005 \*\*No generic anticipated \*\*\*Court hearing January 2006

Many of the drugs for the treatment of ADHD are facing patent expiration. A court hearing to determine the availability of generic Adderall XR is expected to begin early in 2006. Manufacturers of drugs for the treatment of ADHD are taking different pathways. Some are developing novel release mechanisms for the older medications (e.g., Concerta, Mefadate® CR, and the not-yet-approved Methylphenidate). Another pathway is the development of non-scheduled medications that would undergo much less strict regulation and tracking by the U.S. Drug Enforcement Administration (DEA) and would also allow a physician to prescribe refills and call in prescriptions to a pharmacy. Non-scheduled medications in development include GW320659 — a potential competitor to Strattera, as well as AB1089 and SFD-503, which have alternate mechanisms of action. To address the increasing prevalence of obesity in the United States, many new products are being developed, including All 983, a potential competitor to Xenical®, and rimonabant and 1423, both of which decrease appetite.

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## THERAPY CLASS REVIEW

## MIGRAINE PRODUCTS

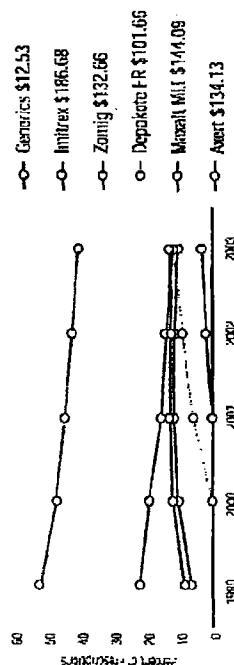
RANK 22

COMPONENTS OF TREND		KEY FACTS
Cost per Prescription	5.0%	PMPV: \$8.77
Inflation	7.1%	Rx PMPV: 0.06
Units per Prescription	-0.6%	
Brand/Generics Mix	0	
Therapeutic Mix	-1.3%	Prevalence of Use: 1.4%
Utilization	-0.6%	Average Cost/Rx: \$139.12
Prevalence	-2.7%	# Rx/User/Year: 4.43
Intensity	2.1%	
New Drugs	1.8%	
TOTAL	6.2%	

Drugs for migraine headache are a well-established class with little generic competition. At 6.1%, drug trend in this class ran well under the overall trend. Utilization was flat, and the cost-per-prescription trend was unremarkable even though the average cost per prescription was high at \$139.12. The new drug in the category, Relpax<sup>®</sup>, contributed 1.7% to the trend numbers.

The first drug in the triptan class, Imitrex<sup>®</sup>, still led in market share, with 40.6% of prescriptions in 2003. However, Imitrex's share has been shrinking in recent years as newer products built their own market shares. Generics played a limited and decreasing role in this category. One drug for migraine prevention, Depakote<sup>®</sup> ER, which gained almost 3 percentage points in 2003, has been showing steady growth since its launch in 2000.

Migraine Products Market Share Trend



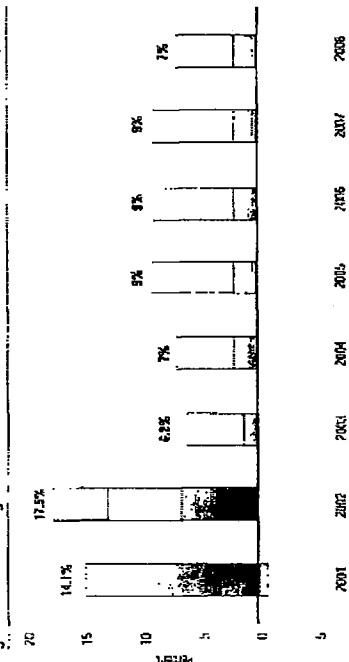
88 express scripts

## THERAPY CLASS REVIEW

## Looking Ahead

Nothing significant should change the market equilibrium in this category until at least 2007, when Intrex is scheduled to lose patent protection. In addition, new products for migraine prevention could affect growth of the triptans. Expecting below-average growth trends to continue, we project annual increases between 7% and 9% through 2008.

Migraine Products Projected Trend



## PIPELINE

Brand	Generic	Manufacturer	Proposed Use	Availability
MT-100 <sup>®</sup>	moscapramide/naproxen	Pfizer	Acute migraine	2004
MT-400 <sup>®</sup>	sumatriptan/naproxen	Pfizer/Celanese/SmithKline	Acute migraine	2006

## PATENT EXPIRATIONS

Brand	Generic	Manufacturer	Patent Expiration
Imitrex <sup>®</sup>	sumatriptan	Celanese/Klinco	June 28, 2007

With the triptan drugs firmly established as the treatment of choice for acute migraine, new drug development in this area is limited. MT-100 and MT-400 are combination products of currently approved drugs (MT-100 contains moscapramide and naproxen; MT-400 contains sumatriptan and naproxen). Several approved drugs are seeking new indications for migraine prevention, including the epilepsy drug Topamax<sup>®</sup> and the anti-wrinkle injection Botox<sup>®</sup>. Although the patent for the first triptan, Intrex, expires in 2007, additional patents may protect the drug from generic competition until at least 2009.

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## THERAPY CLASS REVIEW

## ANTIPSYCHOTICS

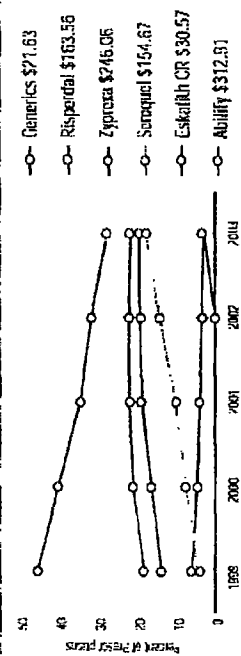
## RANK 21

COMPONENTS OF TREND		KEY FACTS
Cost per Prescription		PPMP: \$8.88
Inflation	18.2%	Rx PMPV: 0.06
Units per Prescription	6.5%	
Brand/Generic Mix	-1.6%	
Therapeutic Mix	-0.1%	
Utilization	13.0%	Prevalence of Use: 1.2%
	9.0%	Average Cost/Rx: \$137.69
Prevalence	3.5%	# Rx/User/Year: 5.54
Intensity	5.3%	
New Drugs	0	
TOTAL	28.8%	

Antipsychotic drug trend increased by 28.8% in 2003, up slightly from 26.9% in 2002. Almost half of the increase was due to therapeutic mix, which — at 13% — was the highest among all therapy classes. Therapeutic mix is typically high for this class of drugs, as more patients shift from older, generic products to newer, atypical antipsychotics. Utilization was also higher than average. Interestingly, intensity of prescriptions grew more than prevalence, which means the market expanded more through current patients than through new patients.

Although generics still led the category in market share, with 27.7% of prescriptions in 2003, the top three atypical antipsychotics (Risperdal<sup>®</sup>, Zyprexa<sup>®</sup> and Seroquel<sup>®</sup>) combined to hold an additional 59.1% of prescriptions. Seroquel and the newest antipsychotic, Abilify<sup>™</sup>, showed the most market share growth, each increasing by about 3 percentage points. Of particular interest was the AWP per prescription difference among the atypicals. In 2003, the cost of Abilify was approximately \$313 — about 50% more than Risperdal or Seroquel. Zyprexa ranged between the extremes, averaging around \$246 per prescription.

## Antipsychotics Market Share Trend



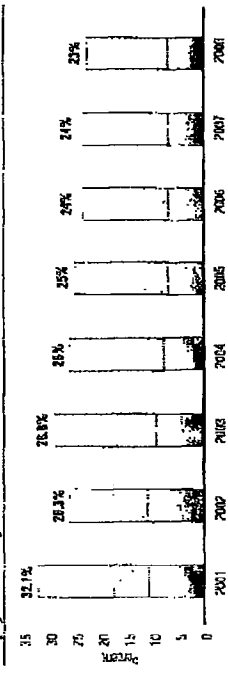
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## THERAPY CLASS REVIEW

## Looking Ahead

Expect current trends to continue. The atypicals are moving beyond schizophrenia therapy and into treatment for other diseases, such as bipolar disorder, where a new group of potential patients is waiting. No generic pressures are expected, and if the higher cost products grow in market share, trend could increase more than predicted. We project an average trend increase of at least 23% annually over the next five years.

## Antipsychotics Projected Trend



## PIPELINE

Brand	Generic	Manufacturer	Proposed Use	Availability
Seroquel <sup>®</sup>	serenidol	Lundbeck	Schizophrenia	2005
	asenapine	Uyemori/Plaza	Schizophrenia	2006
	bilapiprazole	Schering-Plough	Schizophrenia	2006
	asenapine	Schering-Plough	Schizophrenia	2007

## PATENT EXPIRATIONS

Brand	Generic	Manufacturer	Patent Expiration
Risperdal <sup>®</sup>	risperidone	Janssen	June 29, 2008

The market for antipsychotics has continued to grow in recent years, aided by the approval of several atypical products. Several additional atypical products are in the pipeline, and their general mechanism of action does not differ significantly from existing products. One exception is osanatan, which affects neurokinin receptors rather than dopamine receptors. Future growth in this market will also come from new uses separate from psychosis, such as bipolar disorder, Alzheimer's disease and Parkinson's disease. Patent exposure in this class is limited, although legal challenges to the Zyprexa<sup>®</sup> patent cloud the timing of generics.

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## THERAPY CLASS REVIEW

## QUINOLONONES

RANK 20

## COMPONENTS OF TREND

Cost per Prescription	8.4%
Inflation	9.2%
Units per Prescription	0.2%
Brand/Generic Mix	0
Therapeutic Mix	-0.9%
Utilization	6.5%
Prevalence	0.2%
Intensity	0.3%
New Drugs	0
<b>TOTAL</b>	<b>15.4%</b>

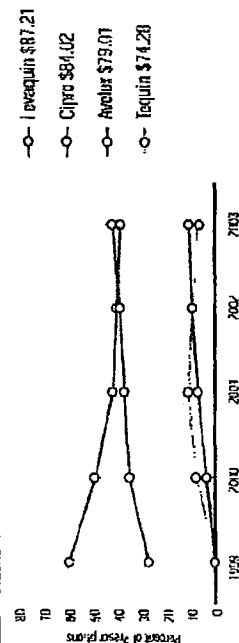
## KEY FACTS

PMPY: \$8.94  
 Rx PMPY: 0.11  
 Prevalence of Use: 6.8%  
 Average Cost/Rx: \$84.20  
 # Rx/User/Year: 1.56

In 2003, quinolone antibiotics, which are used to treat a variety of bacterial infections, showed drug trend growth of 15.4% — closely matching overall trend. Utilization and cost-per-prescription growth also were similar to overall trend. Drugs in this class have not changed significantly since 2000, when two new products were introduced. Inflation was higher than the overall average, most likely in response to the pending generic for Cipro®.

With 42.2% of prescriptions, Levaquin® overtook Cipro for the market share lead in 2003, although Cipro was close behind at 38.9%. The Cipro franchise faced new competition in 2003 with the introduction of a co-licensed brand that was promoted as a generic. This new product, which is known by its generic name of ciprofloxacin hydrochloride, grabbed a 10% market share by the end of 2003. Because it is co-licensed, it is counted as a brand in Cipro's market share, along with the recently released Cipro® XR, which garnered a 3.6% share. True generics to Cipro should enter the market in 2004, potentially ending the confusion.

## Quinolones Market-Share Trend



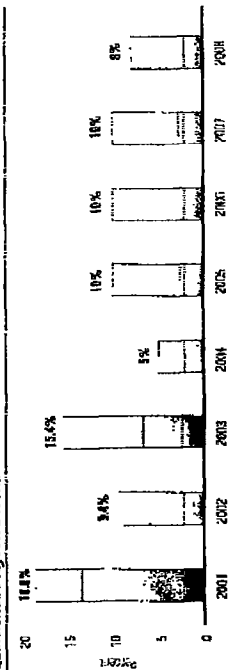
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## THERAPY CLASS REVIEW

## Looking Ahead

Other than the Cipro generic story mentioned previously, current utilization and cost trends should hold steady. We are forecasting a trend for 2004 of 5%, reflecting the entry of generic ciprofloxacin. However, trend should bounce back to average levels around 10% by 2005, before declining again as new generics are introduced.

## Quinolones Projected Trend



## PIPELINE

Brand	Generic	Manufacturer	Proposed Use	Availability
Cipro®	ciprofloxacin	Danach	Drug-resistant infections	2008
Levaquin®	levofloxacin	Bayer	Drug-resistant infections	2008
Avloar®	oxaprolin	Pfizer	Drug-resistant infections	2008
Tequin®	gatifloxacin	GlaxoSmithKline	Drug-resistant infections	2008

The one quinolone in the near-term pipeline, if approved, will likely be reserved for drug-resistant infections. Additional new drug research in this class appears limited. Generics to Cipro will appear in 2004, but other quinolones are patent-protected for several more years.

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## THERAPY CLASS REVIEW

## DECONGESTANTS

RANK 19

COMPONENTS OF TREND	
Cost per Prescription	8.7%
Inflation	9.3%
Units per Prescription	-1.5%
Brand/Generic Mix	-0.2%
Therapeutic Mix	1.2%
Utilization	6.6%
Prevalence	4.1%
Intensity	2.4%
New Drugs	0
TOTAL	15.9%

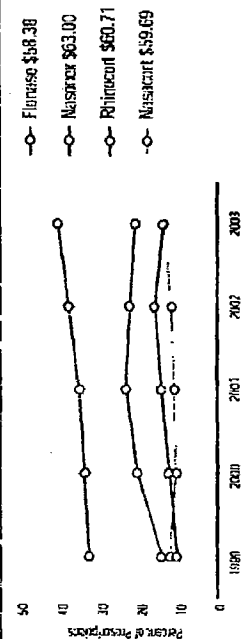
## KEY FACTS

PMP: \$9.69  
 Rx PMP: 0.16  
 Prevalence of Use: 5.6%  
 Average Cost/Rx: \$59.13  
 # Rx/User/Year: 2.9

The decongestant class is represented primarily by nasally-administered products, with nasal steroids accounting for the majority of prescriptions. Overall drug trend for this class in 2003 was 15.9% — right in line with overall trend. Utilization and cost per prescription trends were generally unremarkable. However, prevalence trend increased, which was no doubt related to the Claritin switch and the heavy consumer advertising that accompanied it. As plan sponsors restricted or dropped coverage of anti-histamines, patients shifted to the nasal steroids, which experienced no major formulary status changes during 2003.

Market share in this category was led by the nasal steroid Flonase<sup>®</sup> at 40.6% for 2003, up slightly from 2002. The top four nasal steroids (Flonase, Nasonex<sup>®</sup>, Rhinocort Aqua<sup>™</sup> and Nasacort<sup>®</sup> AQ) represented 88% of all prescriptions in the class. Only one product that was not a nasal steroid had greater than 5% share. The antihistamine nasal spray Astelin<sup>®</sup> increased to 5.7%.

## Decongestants Market Share Trend

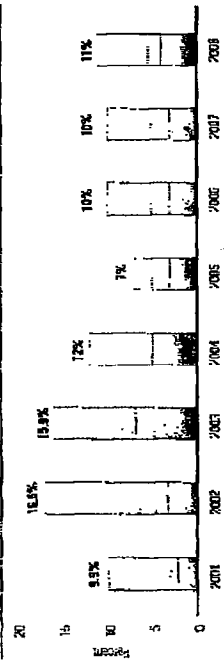


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## Looking Ahead

The patent for Flonase was expected to expire in May 2004, but it is unclear as of this writing if generics will be available at that time. If so, we expect a significant downward shift in cost trends, although the impact would be for only half of 2004. If a generic for Flonase does not make it to market in 2004, expect current cost trends to continue. This is a difficult forecast, but we assume that generics for Flonase will not have a significant impact on overall trend in 2004, and therefore trend for this class will be slightly lower than 2003, at around 12%. If Flonase generics take hold, expect trend in 2005 to dip to 7% before rebounding to the 10% level in later years.

## Decongestants Projected Trend



## PIPELINE

Brand	Generic	Manufacturer	Proposed Use	Availability
Isopropyl nasal	Isopropyl nasal	Isa	Allergic rhinitis	2006
6-Chloro nasal	6-Chloro nasal	GreenSant/Midline	Allergic rhinitis	2007

## PATENT EXPIRATIONS

Brand	Generic	Manufacturer	Patent Expiration
Flonase <sup>®</sup>	Fluticasone nasal	GreenSant/Midline	May 14, 2004

This class primarily contains nasally-administered steroids. It is a relatively mature class with few new products coming to market. The leading product in the class, Flonase, could face generic competition as early as 2004. It is also possible that the entire class of nasal steroids could be switched to over-the-counter status by the end of the decade.

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## THERAPY CLASS REVIEW

## THERAPY CLASS REVIEW

## ANTINEOPLASTICS

RANK 18

COMPONENTS OF TREND	
Cost per Prescription	0.5%
Inflation	11.1%
Units per Prescription	-6.6%
Brand/Generic Mix	-5.8%
Therapeutic Mix	2.8%
Utilization	10.0%
Prevalence	-0.6%
Intensity	10.7%
New Drugs	4.7%
<b>TOTAL</b>	<b>15.1%</b>

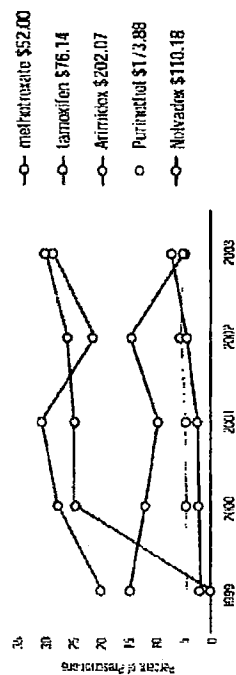
## KEY FACTS

PMPY: \$10.31  
 Rx PMPY: 0.05  
 Prevalence of Use: 0.7%  
 Average Cost/Rx: \$192.02  
 # Rx/Usr/Year: 7.45

Antineoplastics are another therapy class with a high average cost per prescription at \$192.02. However, in 2003 actual cost trends were flat due to significant decreases in units per prescription and brand/generic mix. Utilization growth was at an even 10%, and intensity drove this increase. The continued penetration of novel oral cancer therapies, such as Glivec<sup>®</sup> and Iressa<sup>®</sup>, into cancer treatment regimens is a likely reason for the increase in intensity. New drugs also played a role in antineoplastic trend, driven by the lung cancer drug Iressa.

Market share for antineoplastics was dominated by two generic products, methotrexate and tamoxifen, representing 57.9% of prescriptions. In 2003, methotrexate, which is used for a variety of cancers and rheumatoid arthritis, grew in market share by 3.8 percentage points to reach 29.6%. Tamoxifen, which did not become a "true" generic until February 2003, saw a significant market share gain of 7.5 percentage points to 28.3%. None of the remaining products had a market share of 7% or greater. Due to generic competition, Nolvadex<sup>®</sup>, which is branded tamoxifen, saw the biggest drop (approximately 10 percentage points) in market share.

## Antineoplastics Market-Share Trend



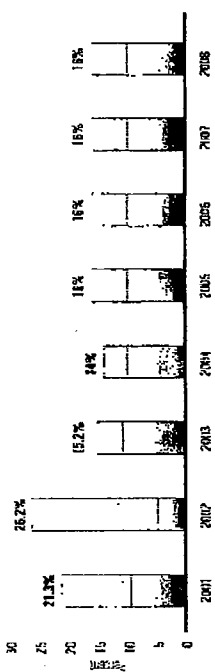
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## THERAPY CLASS REVIEW

## Looking Ahead

Now that one of the leading products has transitioned to a generic, drug trend for antineoplastics should rebound in 2004, as newer, expensive products such as Iressa, Glivec and Temodar<sup>®</sup> are used more commonly. The pipeline is full of new products, but most are injectables that will be administered in the hospital or clinic. Potential generic exposure is limited in coming years. We project that drug trend increases for antineoplastics will be in the range of 16% annually from 2004 through 2008.

## Antineoplastics Projected Trend



## PIPELINE

Brand	Generic	Manufacturer	Proposed Use	Availability
Genosense <sup>™</sup>	abiraterone	Aventis/Glaxo	Solid tumors	2004
Paracetol <sup>®</sup>	tipranavir	Ortho Biotech	HIV-dependent tumors	2005
	relatamine	GlaxoSmithKline	Leukemia/lymphoma	2005
	CC-179	Wyeth	Renal cell carcinoma/ Breast cancer	2005
	tipranavir	Sunovion-Synchro	Non-small cell lung cancer (NSCLC)	2005
Oralvac <sup>™</sup>	ruboxan	Supragen	Pancreatic cancer	2005
Reshield <sup>™</sup>	CC-5013	Calgene	Multiple myeloma	2005
Tarceva <sup>™</sup>	erlotinib	OSI/Genentech Inc	NSCLC	2005
Affinitak <sup>™</sup>	ISIS 2621	ISIS Lilly	NSCLC	2006
	erlotinib	Novartis	Breast cancer/ Prostate cancer	2006
	vedolizumab	Novartis	Metastatic colorectal cancer	2006
Dacogen <sup>™</sup>	decitabine	Sepracor	Myelodysplastic syndromes	2006
Telocyte <sup>™</sup>	ILK286	Idex	Gastric cancer	2006
Vitamin <sup>™</sup>	LM-509	Midmune	Melanoma/Prostate cancer	2007
	SU-11268	Pfizer	Ci-stromal tumor/renal carcinoma	2007
	erlotinib	Pfizer	Glioblastoma	2007
	S12016	GlaxoSmithKline	Solid tumors	2007

## PATENT EXPIRATIONS

Brand	Generic	Manufacturer	Patent Expiration
Paracetol <sup>®</sup>	carbamazepine	Bristol-Myers Squibb	Oct. 14, 2007
Camipras <sup>™</sup>	emecan	Pfizer	Feb. 20, 2008
Dacogen <sup>™</sup>	biadomide	Bristol-Myers Squibb	Oct. 1, 2008

Oncology is probably the most exciting field of pharmaceutical research today, with hundreds of products in development. In 2004, two newly-approved drugs for colon cancer, Avastin<sup>™</sup> and Erbitux<sup>™</sup>, will grab most of the headlines. Lung cancer research, specifically for NSCLC, will result in a number of new drug approvals in the coming years. The oral drug Tarceva is being studied for several cancers, including NSCLC, glioblastoma and pancreatic cancer.

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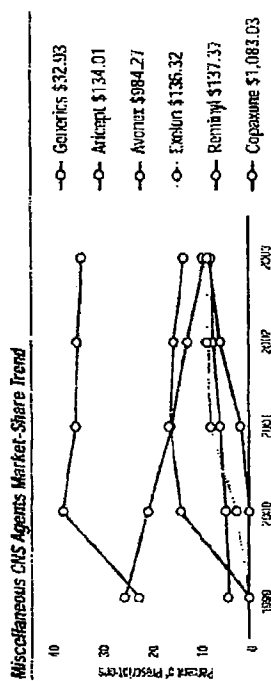
## THERAPY CLASS REVIEW

## MISCELLANEOUS CNS AGENTS RANK 17

COMPONENTS OF TREND		KEY FACTS
Cost per Prescription	13.8%	PMPY: \$11.04
Initiation	8.4%	Rx PMPY: 0.03
Units per Prescription	1.8%	
Brand/Generic Mix	0	
Therapeutic Mix	6.7%	Prevalence of Use: 0.4%
Utilization	12.3%	Average Cost/Rx: \$377.25
Prevalence	3.2%	# Rx/User/Year: 7.03
Intensity	16.0%	
New Drugs	0.3%	
TOTAL	27.9%	

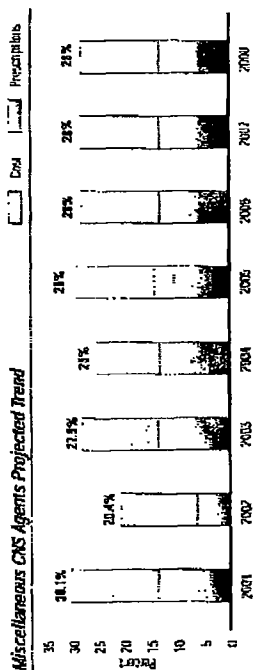
The miscellaneous central nervous system (CNS) drugs are new to the *Drug Trend Report*. In previous years, when the number of prescriptions PMPY was used to rank the classes, the class did not make the list. But when drug costs are taken into account, the class is elevated into the top 25. This class — which includes drugs for Alzheimer's disease, multiple sclerosis (MS), smoking cessation, Parkinson's disease and other conditions — had a significant trend increase of 27.9% in 2003. Trend growth was split almost evenly between utilization and cost per prescription. This class also has one of the highest average costs per prescription at \$377.25, largely due to the expensive MS drugs.

The Alzheimer's drug Aricept®, which led the class in market share for 2003, was one of only two drugs that exceeded 10% of market share. Although it accounted for 33.9% of the class, Aricept's market share actually decreased in 2003 due to greater competition with newer drugs. At 13.2%, Avonex®, a drug for MS, was the other category leader, although its share is also shrinking due to increased competition. Generics do not play a major role in this category, although their market share should increase in 2004 when Zytan® loses patent protection.



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**Looking Ahead**  
Underlying growth trends will continue, as the markets for Alzheimer's disease and MS continue to expand and as average costs per prescription remain high. Look for annual growth to exceed 25% through 2008.



PIPELINE	Brand	Generic	Company	Proposed Use	Availability
Antiepileptic	Aricept	Donepezil	Schwarz	Parkinson's disease	2004
		Donepezil	Novartis	MS	2005
		Donepezil	Novartis	MS	2005
		Donepezil	Novartis	MS	2005
Parkinson's	Avonex	Avonex	Novartis	Parkinson's disease	2005
		Avonex	Novartis	Parkinson's disease	2005
		Avonex	Novartis	Parkinson's disease	2005
		Avonex	Novartis	Parkinson's disease	2005
Smoking cessation	Reminyl	Reminyl	Pfizer	Smoking cessation	2005
		Reminyl	Pfizer	Smoking cessation	2005
		Reminyl	Pfizer	Smoking cessation	2005
		Reminyl	Pfizer	Smoking cessation	2005

PATENT EXPIRATIONS	Brand (generic)	Generic	Manufacturer	Patent Expiration
Cognitive	Aricept	Donepezil	Novartis	Sept. 9, 2007
	Reminyl	Reminyl	Novartis	Dec. 7, 2007

Over the next few years, the key areas of growth in this category include treatment of MS, Parkinson's disease and smoking cessation. In the treatment of MS, several of the new therapies that are anticipated to reach the market will target different disease pathways that lead to the progression of the disease. The first new biologic therapy for MS will likely be Amgen's, a self-administered injectable drug that alters the immune system, decreasing inflammation associated with MS. Other promising therapies for MS include CT144-Ig, CCI-779, MBP-8208 and taurine. In the treatment of Parkinson's disease, Apokyn® (approved in April 2004) and sumatriptan work directly on dopamine receptors while rasagiline prevents the breakdown of dopamine in the brain. Both of these approaches address the decreased dopamine in the brain that is thought to lead to symptoms of the disease.

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## THERAPY CLASS REVIEW

## ORAL CONTRACEPTIVES

RANK 16

## COMPONENTS OF TREND

Cost per Prescription	2.6%
Initiation	7.9%
Units per Prescription	-0.1%
Brand/Generics Mix	-7.8%
Therapeutic Mix	3.3%
Utilization	12.1%
Prevalence	6.1%
Intensity	5.7%
New Drugs	0
<b>TOTAL</b>	<b>15.1%</b>

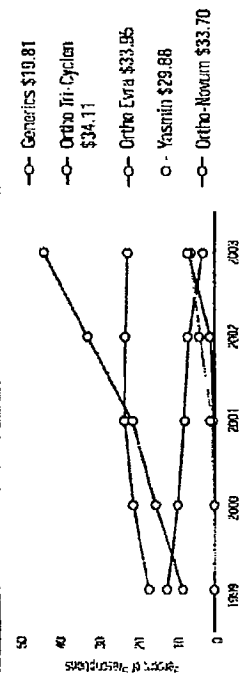
## KEY FACTS

PMPY: \$12.27  
 Rx PMPY: 0.45  
 Prevalence of Use: 5.4%  
 Average Cost/Rx: \$27.14  
 # Rx/User/Year: 8.32

Oral contraceptive drug-trend growth was 15.1% in 2003, down from 19.6% growth in 2002. A slowing in utilization growth was the primary reason for the slowdown, as the prevalence trend dropped another 5 percentage points from last year. Specific reasons for the decrease in prevalence are unclear, but they could include market saturation, fewer branded manufacturers marketing their products and a shift to alternative contraceptive methods. Costs per prescription grew by 2.6%, as a slight increase in therapeutic mix was more than offset by a decrease in brand/generic mix. The average cost per prescription of \$27.14 was the second-lowest among the top 25 classes, and all products in the class were within \$10 of the average cost.

Generic oral contraceptives made their market share move in 2003, growing to a high of 43.8%. Further generic growth is expected since the remaining branded product with double digit market share, Ortho Tri-Cyclen<sup>®</sup>, lost patent protection late in 2003. The contraceptive with the third-highest market share at 6.6% is Ortho Evra<sup>®</sup>, a transdermal patch, not an oral contraceptive.

## Oral Contraceptives Market-Share Trend



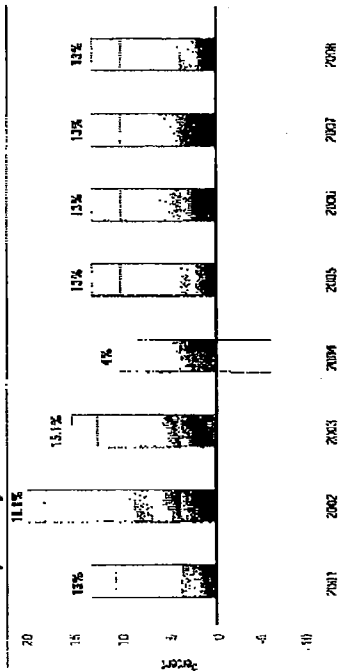
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## THERAPY CLASS REVIEW

## Looking Ahead

As stated earlier, the move of Ortho Tri-Cyclen to generics could result in generic market share approaching 60% in 2004. The number of branded oral contraceptives is dwindling, which should keep overall PMPY costs low. After a dip to about 4% in 2004 to account for generics, we project average growth for the class to be in the 13% range from 2005 to 2008.

## Oral Contraceptives Projected Trend



## PIPELINE

Brand	Generic	Manufacturer	Proposed Use	Availability
Yasmin <sup>®</sup> 20	ethinyl estradiol/ drospirenone	Bayer	Contraception	2004
Seasonale <sup>®</sup> 1c	ethinyl estradiol/ levonorgestrel	Bayer	Contraception, extended-cycle	2006
	DP3	Bayer	Contraception, extended-cycle	2006
	ethinyl estradiol/ trimegestone	Bayer	Contraception	2007+

With the approval of the extended-cycle product Seasonale<sup>®</sup> in 2003, the FDA finally approved an oral contraceptive dosage regimen that was common practice for many years. Other extended-cycle products are in development, including one that uses lower doses of the hormones found in Seasonale. The bigger stories in this category are the availability of several new generic products and the potential switch of emergency contraceptives to over-the-counter status in all states, which could occur as early as 2004.

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## THERAPY CLASS REVIEW

## BETA BLOCKERS

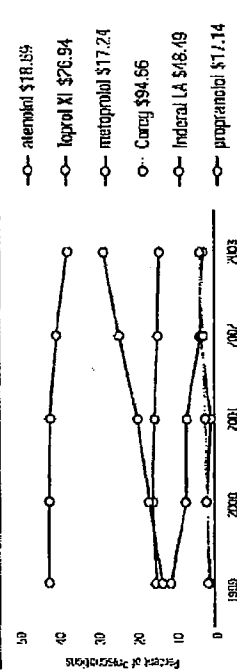
RANK 15

COMPONENTS OF TREND		KEY FACTS
Cost per Prescription	9.6%	PMPY: \$13.01
Initiation	6.8%	Rx PMPY: 0.48
Units per Prescription	0.6%	
Brand/Generic Mix	0.6%	
Therapeutic Mix	2.6%	
Utilization	13.8%	Prevalence of Use: 5.5%
Prevalence	11.1%	Average Cost/Rx: \$26.90
Intensity	2.4%	# Rx/User/Year: 8.73
New Drugs	0	
TOTAL	24.7%	

In contrast to calcium channel blockers, beta blockers had a healthy trend increase in 2003, reaching 24.7%, up from 19.6% in 2002. Almost all of the increase was due to greater utilization. The release of updated JNC-VII hypertension guidelines in 2003 likely had a positive impact on beta blocker use, as did the ever-increasing population of hypertensive patients. Even though a 24.7% increase in trend seems significant, the average cost per prescription of \$26.90 was the lowest of the top 25 therapy classes.

The branded product Toprol XL<sup>®</sup> continued to gain market share at the expense of generics, and its overall market share of 28.4% in 2003 was more than double its 1999 share. Still, two generics, atenolol and metoprolol, represented 51.9% of overall share.

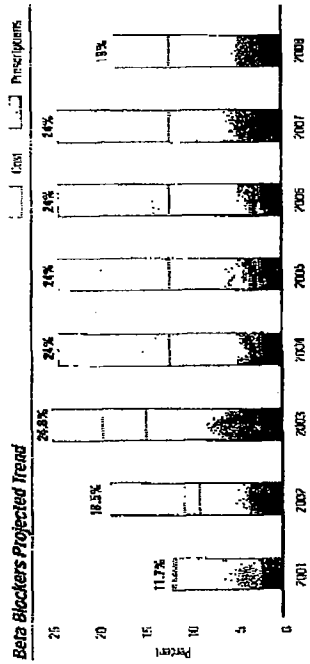
Beta Blockers Market Share Trend



## THERAPY CLASS REVIEW

## Looking Ahead

We expect new guidelines and the increased prevalence of hypertension to continue driving healthy drug trend gains in the beta blocker therapy class. Annual increases of 24% are projected through 2007, with moderation to about 18% in 2008.



PIPELINE		Manufacturer	Proposed Use	Availability
Brand	Generic	Quesada	Hypertension	2004

## PATENT EXPIRATIONS

Brand	Generic	Manufacturer	Patent Expiration
Carag	carvedilol	GlaxoSmithKline	Sept. 5, 2007

The beta blockers are a mature class of drugs with mostly generic products. The one pipeline product, rolovidol, which is approved in other countries, works by affecting nitric oxide release in addition to beta blockade. It is thought that rolovidol's effect on nitric oxide results in improved vasodilation, but the FDA has not announced how it will analyze this information if or when it approves the drug for use in the United States. With regard to patent expirations, Carag is set to face generic competition in 2007, and Toprol XL<sup>®</sup>, the leading beta-blocker, could face generics as early as 2004, but more likely not until 2009 due to additional patents protecting the drug.

## CALCIUM BLOCKERS

## RANK 14

COMPONENTS OF TREND	
Cost per Prescription	1.9%
Inflation	3.2%
Units per Prescription	-0.1%
Brand/Generic Mix	-2.1%
Therapeutic Mix	0.9%
Utilization	1.7%
Prevalence	1.3%
Intensity	0.4%
New Drugs	0
TOTAL	3.7%

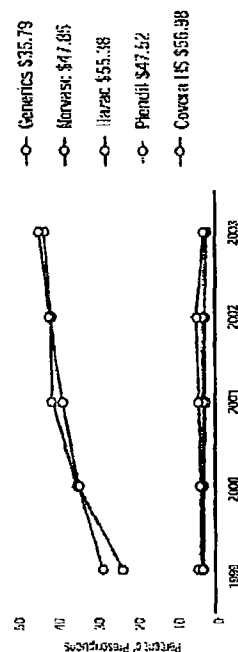
## KEY FACTS

PMPY: \$14.21  
 Rx PMPY: 0.32  
 Prevalence of Use: 3.6%  
 Average Cost/Rx: \$44.55  
 # Rx/User/Year: 8.9

Drug trend for calcium channel blockers stayed remarkably constant between 2002 and 2003. The overall trend of 3.7% was up from 1.2% in 2002, an increase almost entirely driven by a small rise in utilization and inflation. Because the class is dominated by generics and by one brand, changes in brand/generic mix and therapeutic mix were not significant. No new indications or clinical guidelines are expected that would contribute to significant growth in this class.

Norvasc<sup>®</sup> remained the only branded product with double-digit market share. In 2003 it reached a high of 44.3%. Generics were also increasing in share, even more dramatically than Norvasc, nearly doubling from 23.5% in 1999 to 43.1% in 2003. Norvasc and the generic products combined for 87.4% of all prescriptions in the class.

Calcium Blockers Market Share Trend



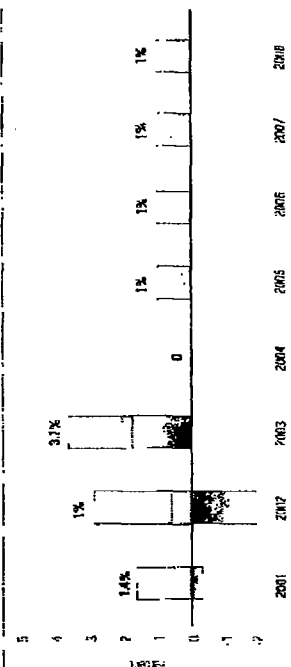
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## THERAPY CLASS REVIEW

## Looking Ahead

The Norvasc franchise will continue to dominate until 2007, when its patent expires. In late 2003 the FDA approved Amilor<sup>®</sup>, a different salt formulation of Norvasc, but in February 2004 a federal court ruled that Amilor violated Norvasc patents, so its market introduction is unlikely to be soon. Cardizem<sup>®</sup> LA, released in 2003, may also have an impact in the future because it is one of the few diltiazem products still being marketed actively. We expect no growth in 2004, followed by only minimal levels of about 1% per year through 2008.

Calcium Blockers Projected Trend



## PIPELINE

Brand	Generic	Manufacturer	Proposed Use	Availability
Amilor <sup>®</sup>	Isradipine	Forest	Hypertension	2006
Cardizem <sup>®</sup> LA	IS isradipine	Sandoz	Hypertension	2007

## PATENT EXPIRATIONS

Brand	Generic	Manufacturer	Patent Expiration
Amilor <sup>®</sup>	Isradipine	Forest/Horiz	Feb. 21, 2004
Norvasc <sup>®</sup>	amlodipine	Pfizer	Jan. 31, 2007

Calcium channel blockers are becoming a mature class with few new drugs in the pipeline. Primarily intended for convenience, Cardizem<sup>®</sup>, approved in January 2004, is a combination of the calcium channel blocker Norvasc (amlodipine) with the antihypertensive Lipitor. A new amlodipine product, Amilor<sup>®</sup>, which differs from Norvasc in that it is produced using a different salt formulation, was expected on the market in 2004, but a court ruling has delayed its entry indefinitely.

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## THERAPY CLASS REVIEW

## ANTIHISTAMINES

RANK 13

COMPONENTS OF TREND	
Cost per Prescription	-7.3%
Initiation	3.0%
Units per Prescription	0.5%
Brand/Generic Mix	0.4%
Therapeutic Mix	-10.1%
Utilization	-14.6%
Prevalence	-17.3%
Intensity	3.3%
New Drugs	0
TOTAL	-20.9%

## KEY FACTS

PMP: \$17.11

Rx PMP: 0.31

Prevalence of Use: 8.8%

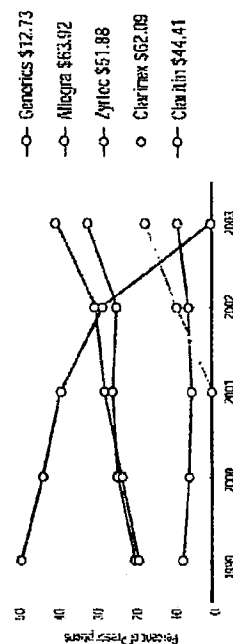
Average Cost/Rx: \$54.65

# Rx/User/Year: 3.56

To no one's surprise, overall drug trend for the antihistamine class fell significantly in 2003 with the introduction of OTC Claritin®. All components of trend were lower than in 2002, and the decrease in the cost per prescription was the greatest of the top 25 therapy classes, at -7.3%. In addition, a therapeutic mix change of -10.1%, the lowest of the top 25 classes, was due to a shift in prescriptions from Claritin to the remaining second-generation antihistamines, all of which retained prescription-only status at prices less than Claritin's.

With one major branded product removed from the equation, the remaining brands each picked up market share in 2003. Allegra® continued to be the market leader at 40%, and the second generation antihistamines continue to hold about 90% of the prescription volume in the class. Generic market share rose slightly in 2003 due to an unexpected increase in the use of promethazine, an older antihistamine that is also used to control nausea and to treat insomnia.

## Antihistamines Market Share Trend

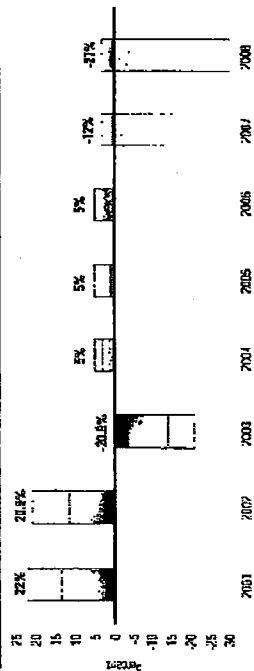


70 express scripts

## Looking Ahead

With no new products in the pipeline and pressure building for additional products to go over-the-counter (OTC), it is unlikely that we will see significant drug trend growth in the coming years. In 2004, Claritin will not be part of the prescription drug trend equation so an uptick in trend is likely to be observed, but utilization probably will not return to past levels. We forecast growth of only 5% per year in 2004 to 2006, followed by negative trend thereafter, as additional products lose patent protection and/or go OTC. Plans that actively manage the class will see even greater savings.

## Antihistamines Projected Trend



## PIPELINE

Brand	Generic	Manufacturer	Proposed Use	Availability
Allegra®	loratadine	Aventis	Prescription	2006
Claritin®	desloratadine	Schering-Plough	OTC	2006
Zyrtec®	cetirizine	Pfizer	OTC	2006

## PATENT EXPIRATIONS

Brand	Generic	Manufacturer	Patent Expiration
Allegra®	loratadine	Aventis	July 21, 2007
Claritin®	desloratadine	Schering-Plough	Dec. 25, 2007
Zyrtec®	cetirizine	Pfizer	Dec. 25, 2007

The one product in this pipeline category is not an antihistamine but a biotechnology agent. No antihistamines in the pipeline appear likely to make it to market since the most recent promising product, Sollara™ (lecasinimide), was held up at the FDA and further development appears unlikely. With new drug development at a standstill, OTC and/or line extensions become developmental opportunities. While it is unknown whether the remaining antihistamines will be switched to OTC status, the success of Claritin® OTC and the recent approval of Singulair® for allergic rhinitis will likely curb continued growth in this class. In addition, patent expirations will play a major role, with the entire category potentially becoming generic within the next four to five years.

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## THERAPY CLASS REVIEW

## DERMATOLOGICALS

## RANK 12

## COMPONENTS OF TREND

Cost per Prescription	10.9%
Inflation	8.4%
Units per Prescription	3.3%
Brand/Generic Mix	-4.5%
Therapeutic Mix	3.8%
Utilization	1.3%
Prevalence	-0.1%
Intensity	1.3%
New Drugs	0.5%
<b>TOTAL</b>	<b>12.8%</b>

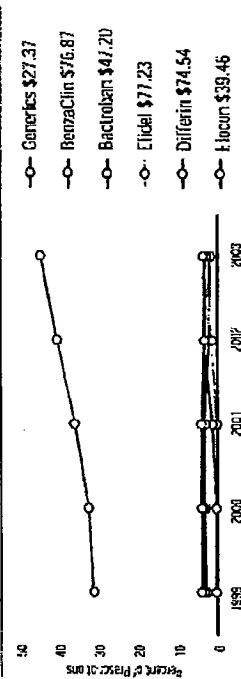
## KEY FACTS

PMPPY: \$17.13
Rx PMPPY: 0.31
Prevalence of Use: 12.6%
Average Cost/Rx: \$55.34
# Rx/User/Year: 3.22

Dermatologicals are a relatively stable class from year to year, with overall trend typically driven by price inflation. No difference was seen in 2003, as inflation represented approximately two-thirds of overall trend growth. Utilization was flat, and the therapeutic mix increase caused by new drugs such as Eidel<sup>®</sup> was offset by a negative brand/generic mix.

Generics dominated market share in the class, reaching a five year high of 44.5% in 2003. The top branded product, Benzac<sup>®</sup>, had only 3.5% of market share, reflecting the large size of this therapy class. Eidel, released in 2002, had the biggest market share gain of any branded product in the class, growing from 1.4% to 3.2% of prescriptions.

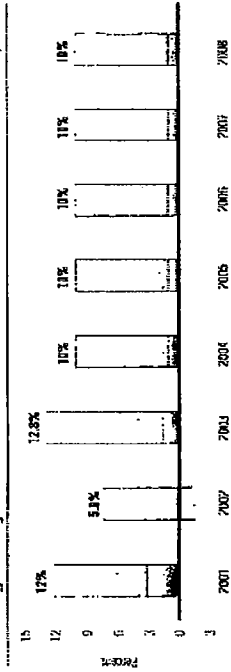
## Dermatologicals Market-Share Trend



## Looking Ahead

The overall drug trend for dermatologic products shows little change from year to year, and we expect that trend to continue, with growth rates holding steady at 10% over the next five years.

## Dermatologicals Projected Trend



## PIPELINE

Brand	Generic	Manufacturer	Proposed Use	Availability
Azela <sup>®</sup>	clindamycin 1% foam	Corbion	Acne	2004
Taurac <sup>®</sup>	tauracaine gel	Allergan	Psoriasis	2004
	SP-275833	GlaxoSmithKline	Bacterial skin infections	2006
Fluorac <sup>®</sup>	clindamycin	Procyon/Biovil	Hypertrophic scarring	2007
	clindamycin	Serono	Psoriasis	2007
	intercept injectable	Micrologix Biotech	Acne	2007+
Dimeric <sup>®</sup>	TAH-594AN	ATI Dermatics	Keratoma pigmentosum	2007
Periban <sup>®</sup>	TAK liposome lotion	Callicote	Psoriasis	2007
	cyclosporine conjugate (topical)			

## PATENT EXPIRATIONS

Brand	Generic	Manufacturer	Patent Expiration
Curio <sup>®</sup> cream	fluorocaine	GlaxoSmithKline	May 14, 2004
Ultrasol <sup>®</sup>	fluorocaine	Westwood	June 10, 2004
crenabimant	hydrocortisone prednisolone	CellCept/Alana	Feb. 26, 2005
Paridel <sup>®</sup> cream	skin substitute	Organogenesis	May 77, 2005
Apilip <sup>®</sup>	calcipotriene	Bristol Myers Squibb	June 29, 2008

Several significant developments in dermatology took place in 2003, so the new drug pipeline is relatively quiet. Two new biotechnology products, Amivive<sup>®</sup> and Rapiva<sup>®</sup>, received FDA approval in 2003 for the treatment of psoriasis, while a third product, Eubel<sup>®</sup>, submitted an application for a similar indication. Two additional drugs already on the market, Remicade<sup>®</sup> and Humira<sup>®</sup>, are being studied for their effectiveness in psoriasis. Of note in 2004 is the potential approval of Taurac<sup>®</sup> for the treatment of psoriasis. Taurac is currently available in cream and gel formulations for the treatment of acne, but an oral formulation is under review.

## THEORY CLASS REVIEW

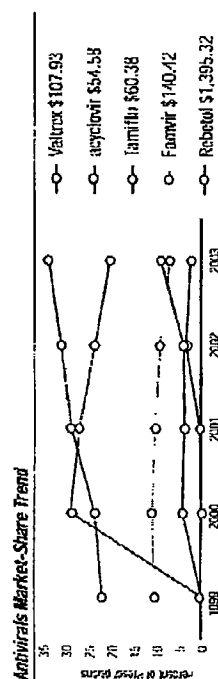
## ANTIVIRALS

**RANK 11**

COMPONENTS OF TREND		KEY FACTS	
Cost per Prescription	-1.7%	PMPY: \$17.69	
Initiation	6.5%	Rx PMPY: 0.07	
Units per Prescription	-0.6%	Prevalence of Use: 2.4%	
Brand/Generic Mix	-0.1%	Average Cost/Rx: \$243.79	
Therapeutic Mix	-7.1%	# Rx/User/Year: 2.98	
Utilization	12.7%		
Prevalence	22.3%		
Intensity	-8.3%		
New Drugs	0.3%		
TOTAL	11.6%		

In previous editions of the *Drug Trend Report*, antivirals were seldom part of the discussion because the volume of prescriptions did not place the top 25 based on utilization. However, this year's Report ranks the classes by TMPV spend, and antivirals are among the top 25 by that measure. Trend in 2003 for antivirals was modest, reaching 11.6%. Utilization growth was actually higher than overall trend, at 12.7%, with the prevalence of users growing by a remarkable 22.9%. This significant increase in prevalence was due to the influenza outbreak in the fall of 2003 and the resultant use of anti-flu medications, such as "famflu". Actual exist-per-prescription trends were negative in 2003, partly due to less expensive drugs for herpes, hepatitis and HIV. However, the class carried one of the highest average costs per prescription at \$243.79.

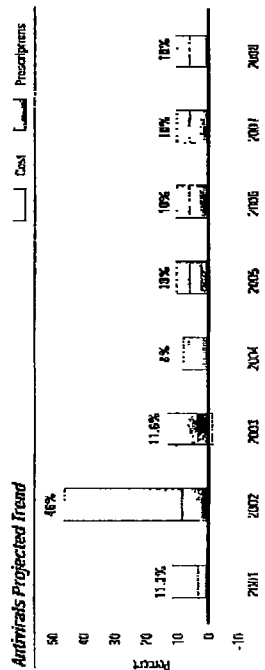
The herpes drug Valtrex® continued to lead the category in terms of market share, with a 33.9% share in 2003, up 2.8% from 2002. Famvir®, a similar medication, bore the brunt of Valtrex's increased market share, falling to 7.2%. Cost-per-prescription trends, which grew by approximately 40% in 2002, were significantly lower in 2003, due to the impact of lower-priced hepatitis C products, Pegaseq® and Coppegas™, which grew market share at the expense of its higher-priced competitors PegC-Intron® and Relatop®. Tamiflu showed the most market share gain if any drug in the class, rising by 5% to reach 9.1% of prescriptions.



## 56. `cross` scripts

## Looking Ahead

Generic competition for the hepatitis drug Rebetol should help contain cost-per-prescription trends; and if flu vaccine supplies are sufficient, Tamiflu use should revert to normal in 2004. We expect overall trend to return to pre-2002 levels, with an average trend increase of 10% through 2008.



Pipeline	Brand	Generic	Manufacturer	Proposed Use	Availability
	Vecavir <sup>®</sup> Fentivir <sup>™</sup>				
		lanicovir embiciclovir	Gilead	HIV	2005
		rilovir	IsaBio/ Myers Squibb	Hepatitis B	2005
		tipranavir	BioCringer Ingelheim	HIV	2005
		HY-055	Modular	Hepatitis A	2006
		capravirine	Pfizer	HIV	2006
		Spr-754	Silico	HIV	2006
		trichuridine	Novartis/Genent	Hepatitis B	2007
		UK-421,857	Pfizer	HIV	2007 <sup>1</sup>

The clinical approach to treating HIV infection has not changed in recent years; what has changed is the so-called "pill burden," so named because multidrug therapy can require a great number of pills per day. Recent long-acting and combination approvals have helped ease the pill burden, and while upcoming pipeline drugs appear to be complementary therapies, Ipravir, capravirine and the Viread/Intavi combination product all work similarly to existing therapies. The bigger change may occur later this decade, when new therapies, such as C-C chemokine receptor type 5 (CCR5) antagonists and integrase inhibitors, reach the market. Hepatitis C treatment appears stable near-tail with existing products; the next cycle of products is a few years away. Several new antiviral vaccines are in development, including vaccines for herpes zoster (shingles), rotavirus (infant diarrhea) and human papilloma virus (precursor to cervical cancer).

## THERAPY CLASS REVIEW

## ANTICONVULSANTS

RANK 10

## COMPONENTS OF TREND

Cost per Prescription	13.6%
Inflation	7.5%
Units per Prescription	-1.9%
Brand/Generic Mix	-0.9%
Therapeutic Mix	8.7%
Utilization	13.3%
Prevalence	12.1%
Intensity	1.2%
New Drugs	0
<b>TOTAL</b>	<b>28.9%</b>

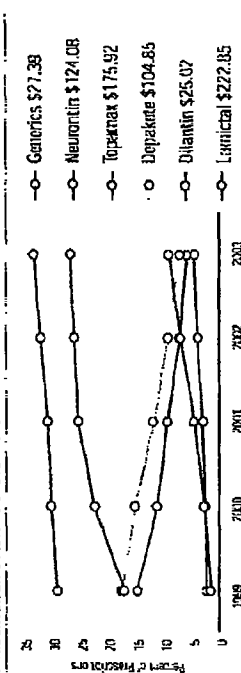
## KEY FACTS

PMPP: \$18.33  
 Rx PMPP: 0.20  
 Prevalence of Use: 2.7%  
 Average Cost/Rx: \$93.91  
 # Rx/User/Year: 1.35

Drug spend in the anticonvulsant therapy class grew by 28.9% in 2003, down slightly from 33.5% in 2002. Slower inflationary trends and slightly lower utilization growth helped drive the slower growth. Overall growth is still significant, however, as the use of these products expands beyond the treatment of epilepsy to other conditions, such as migraine, neuropathic pain and bipolar disorder. Therapeutic mix was unchanged in 2003, at 8.7%, as older epileptic drugs gave way to newer therapies.

Despite the significant contribution of therapeutic mix to overall drug trend, generics still led the class in market share, with just over 33% in 2003. The top branded product, Neurontin®, continued to be significantly ahead of the other brands in terms of market share. The differential in average cost per prescription continued to grow, with generics averaging \$27.39 per prescription and the various brands ranging up to \$223 per prescription. Also noteworthy is that market shares grew for all but one of the branded products that have an average cost per prescription of greater than \$100.

## Anticonvulsants Market Share Trend

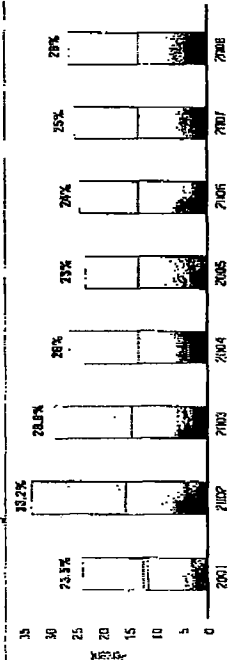


64 express scripts

## Looking Ahead

We expect cost-per-prescription and utilization trends in this class to continue increasing, as the market continues to expand and more people are treated. In addition, a significant new product, Lyrica®, likely will be added to this class in 2004, perhaps driving utilization up even further. Exposure to generics is limited, although generics for Neurontin could appear as early as 2004. Given these factors, we expect annual trend increases of about 25% in the coming years.

## Anticonvulsants Projected Trend



## PIPELINE

Brand	Generic	Manufacturer	Proposed Use	Availability
Lyrica®	pregabalin	Pfizer	Epilepsy	2004

## PATENT EXPIRATIONS

Brand	Generic	Manufacturer	Patent Expiration
Neurontin®	gabapentin	Pfizer	Pending
Topamax®	topiramate	Janssen & Janssen	March 26, 2005*
Depakote®	divalproex sodium	Abbott	July 29, 2008

\*Company filed for USPTO patent extension, which may protect until 2008

The only significant new drug in the anticonvulsant pipeline is Lyrica, which is expected on the market in the latter half of 2004. Lyrica is similar to Neurontin. In addition to epilepsy treatment, pregabalin is being studied for treating neuropathic pain and anxiety disorders. Other new products in this class are limited to line extensions and new indications for existing products.

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## THERAPY CLASS REVIEW



## NARCOTIC ANALGESICS

RANK 9

## COMPONENTS OF TREND

Cost per Prescription	16.1%
Inflation	5.8%
Units per Prescription	6.2%
Brand/Generic Mix	-6.8%
Therapeutic Mix	11.0%
Utilization	7.4%
Prevalence	4.5%
Intensity	2.9%
New Drugs	0
TOTAL	24.8%

## KEY FACTS

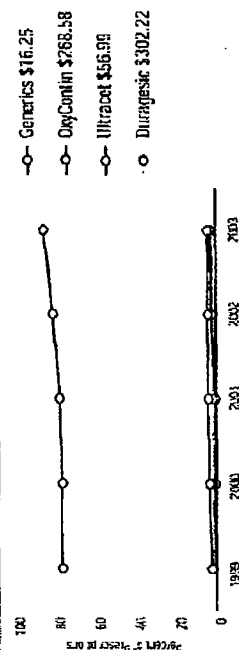
PMPY: \$18.70  
Rx PMPY: 0.50

Prevalence of Use: 15.6%  
Average Cost/Rx: \$37.45  
# Rx/User/Year: 3.2

Overall drug trend in the narcotic analgesic therapy class was 24.8% in 2003, up from 21.9% in 2002. The increased trend was driven by a 16.1% increase in the cost per prescription, not by utilization, which was slightly down in 2003. Higher per-prescription costs were a result of increased inflation, therapeutic mix changes and minor units per prescription. At 11%, therapeutic mix trend was especially high, as the more expensive branded products, OxyContin<sup>®</sup>, Ultracet<sup>®</sup> and Duragesic<sup>®</sup>, each increased in market share.

In terms of actual prescriptions, generics overwhelmingly dominated this class, with an 86.1% market share. A generic, hydrocodone/acetaminophen, was the leading narcotic analgesic in 2003, with a market share of 33.3% and an average cost of \$9.87 per prescription. In contrast, the leading branded drug, OxyContin, had a market share of 3.8% and an average cost per prescription of \$268.58.

## Narcotic Analgesic Market-Share Trend



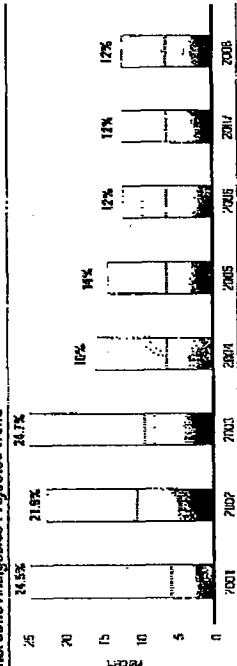
52 express scripts

## THERAPY CLASS REVIEW

## Looking Ahead

Each of the three leading branded products has patent expiration issues starting as early as 2004, so the cost-per-prescription trends should start heading downward in the coming years. Utilization growth is harder to predict, but it is likely to go up from 2003 levels. We predict average trend increases in the range of 20% for 2004, but declining to 12% by 2006 as new generics take hold.

## Narcotic Analgesics Projected Trend



## PIPELINE

Brand	Generic	Manufacturer	Proposed Use	Availability
Dilaudid-CR <sup>®</sup>	hydrocodone	Abbott	Chronic pain	2005
	hydrocodone	Watson	Pain	2006
	hydrocodone	Fred	Moderate-to-severe pain	2005
	hydrocodone	Pain Therapeutics	Moderate-to-severe pain	2006

## PATENT EXPIRATIONS

Brand	Generic	Manufacturer	Patent Expiration
Duragesic <sup>®</sup>	oxycodone	Abbott	July 23, 2004/Jan. 23, 2005
OxyContin <sup>®</sup>	oxycodone, CR	Purdue	Pending
Ultracet <sup>®</sup>	hydrocodone/acetaminophen	Ortho-McNeil	Aug. 15, 2004

Generic products still dominate prescriptions in this therapy class, which is reflected in the small number of pipeline products, most of which are reformulations. Oxycodone is a new form of analgesic currently approvable at the FDA. The more significant story in this class is patent expirations for two key products: Duragesic and OxyContin. Generic competition to Duragesic could begin as early as 2004. A potential successor to Duragesic is in development but is not close to being marketed. The Duragesic patent is set to expire in July 2004, but a six-month pediatric exclusivity extension could preclude generics from being launched until January 2005, pending the outcome of litigation. At least one generic has been approved by the FDA, and the company that makes it plans to market it in July, regardless of any court rulings. The FDA has also granted final approval for OxyContin generics, and at least one manufacturer has launched a generic version, despite unresolved legal issues.

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## THERAPY CLASS REVIEW

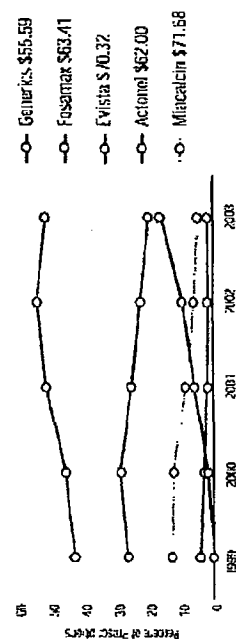
## MISCELLANEOUS ENDOCRINES RANK 8

COMPONENTS OF TREND		KEY FACTS
Cost per Prescription	2.7%	PMPP: \$19.03
Inflation	4.9%	Rx PMPP: 0.19
Units per Prescription	0.1%	
Brand/Generic Mix	0.3%	
Therapeutic Mix	-2.6%	
Utilization	21.8%	Prevalence of Use: 2.4%
Prevalence	14.9%	Average Cost/Rx: \$97.74
Intensity	6.0%	# Rx/User/Year: 8.21
New Drugs	2.0%	
TOTAL	27.1%	

The miscellaneous endocrines class primarily contains drugs for osteoporosis, infertility and growth hormone deficiency. Traditionally, this class shows one of the greatest increases in drug trend from year to year, and 2003 was no exception; the overall trend of 27.1% was a 1.5% increase from 2002. Utilization growth again led the way, with a 21.8% increase from 2002. The movement away from hormone replacement, due to the aging of the population and better awareness, likely led to the increased trend. New drugs, specifically the injectable osteoporosis drug Forteo®, contributed 2% of the trend increase in the class and \$0.22 in overall PMPP costs. Although the average cost per prescription for this class was \$97.74, the osteoporosis drugs, with the exception of Forteo at \$2,131 per prescription, averaged between \$62 and \$70 per prescription.

Even though this class represents a broad range of drugs, prescription market share is heavily weighted to the drugs for osteoporosis. Four of them, Fosamax®, Evista®, Actonel® and Miacalcin®, represented 93.1% of prescriptions in the class. The market shares for both Fosamax and Evista declined in 2003, largely due to the growth of Actonel. Generics have little presence in the class, achieving only a 2% market share in 2003.

## Miscellaneous Endocrines Market-Share Trend

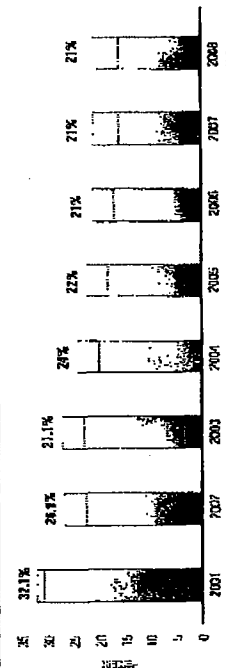


60 express scripts

## Looking Ahead

Other than market share shifts among the leading products, little else is expected to change. Generics will not play a significant role until 2008, when the Fosamax patent is scheduled to expire. Even then, the weekly version of Fosamax will still have several years of patent protection remaining. The aging of the population, the continued undertreatment of osteoporosis and the shift away from hormone replacement therapy should keep utilization growth high. We expect overall trend to be similar to current levels, at around 24% in 2004, about 22% in 2005 and then dropping slightly to about 21%.

## Miscellaneous Endocrines Projected Trend



## PIPELINE

Brand	Generic	Company	Proposed Use	Availability
Tivolis®	lanthanum	Serono	Osteoporosis	2004
Teriparatide®	teriparatide	Genentech	Osteoporosis	2005
Somaviv®	hGH + IGF-1RHP-3	Inamed	Growth hormone	2005
Repro®	danazol	Roch	Osteoporosis	2005
Pross®	parathyroid hormone	NPS	Osteoporosis	2005
	lactadion	Pfizer	Osteoporosis	2006
	teriparatide	Wyeth	Osteoporosis	2006
	teriparatide	Serono	Osteoporosis	2007

## PATENT EXPIRATIONS

Brand	Generic	Manufacturer	Patent Expiration
Forteo®	teriparatide	Serono	June 28, 2005
Pross®	teriparatide	Merck	June 19, 2006

Prescriptions in this widely-defined category have been dominated by osteoporosis drugs in recent years, and this trend is likely to continue. Repro is a new entrant into the bisphosphonate field, and although it was approved in 2003, launch plans are delayed as additional research on a once-monthly dose is conducted. Pross® is an injectable, full-strength parathyroid hormone for the treatment of osteoporosis. Once available, this product will compete with Forteo. The selective estrogen receptor modulator (SERM) Evista may face at least two new competitors, teriparatide and lactadion, in the coming years. This category could also grow depending on the results of the STAR trial, which pits Evista against tamoxifen for the prevention of breast cancer. Somaviv is an insulin growth factor complex being studied for a number of uses, including growth hormone insensitivity syndrome and type 1 diabetes.

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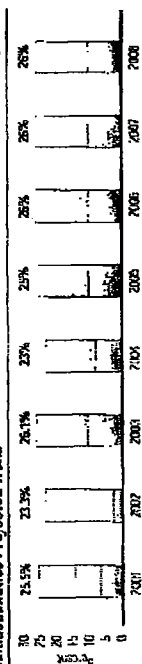


## THERAPY CLASS REVIEW

## Cooking Ahead

Future growth in the antitubercular class largely depends on how the FDA deals with off-brand inhalers. While all of the generic off-brand inhalers contain cancer-damaging chlorofluorocarbons (CFCs), which are to be phased out over the next several years and replaced with CFC-free products, that phase-out is not likely to be final in 2004; but when it does go into effect, the vast per prescription in this class will rise substantially as the discontinued generic inhalers will be replaced by CFC-free branded inhalers. In the short term, we expect a continued rise in utilization with stabilization in the average growth of the cost per unit, so we are forecasting annual trend increases in the 25% range over the next five years.

**Antisynthetics Projected Trend**



**PIPELINE**

Brand	Generic	Manufacturer	Proposed Use	Availability
Akrenspan <sup>®</sup>	flunitrazepam	Toront	Asstina	2004
Akrenspan <sup>®</sup> MIX	flunitrazepam	Toront	Asstina	2004
Alone <sup>®</sup>	albuterol HFA	Wat	Asstina	2004
Alone <sup>®</sup> HFA	albuterol sodium	Wat	Asstina	2004
Alone <sup>®</sup> HFA	albuterol sodium	Wat	Asstina	2004
Alone <sup>®</sup>	chlorzoxazone	Wat	CTEP	2004
Akrenspan <sup>®</sup>	carbamazepine	Schering-Plough	Asstina	2004
Akrenspan <sup>®</sup>	carbamazepine	Schering-Plough	Asstina	2004
Docus <sup>®</sup>	ranitidine	Pfizer/Alkermes	Asstina (COP)	2006
Symbrion <sup>®</sup>	gabapentin	Schering	Asstina	2006
Symbrion <sup>®</sup>	gabapentin	Schering	Asstina	2006

## PATENT EXPIRATIONS

Br and Form <sup>a</sup>	Generic	Manufacturer	Patent Expiration
Fluorene <sup>b</sup>	fluoxetine	GlaxoSmithKline	May 14, 2005
Fluorene <sup>b</sup>	reserpine <sup>c</sup>	Parke-Davis	April 2, 2007
Sarcosine <sup>c</sup>	salmonell	GlaxoSmithKline	Oct. 12, 2008
Adenine <sup>d</sup>	butylresorcinol/salmonell	GlaxoSmithKline	Oct. 12, 2008

The quality of the asthma/COPD pipeline is mixed, with several novel products balanced by a number of reformulations. New drug discussions are highlighted by Spiriva (approved January 2004), which is a new, once-daily inhaler for COPD. Other new drugs for COPD include the phosphodiesterase-4 (PDE-4) inhibitors roflumilast and cilomastat, which are oral drugs. PDE-4 inhibitors have been the subject of some skepticism due to questions surrounding safety and efficacy, so their ultimate market penetration is unclear. A number of asthma inhalers are being reformulated with CFC-free propellants, as traditional CFC-based products will eventually be removed from the market. Overall, the asthma pipeline is dominated by beta-agonists and inhaled steroids, as several new classes of compounds (leukotriene agonists, integrin antagonists, anti-leukotrienin antagonists) are in development, but they are not close to being marketed. Patient inhalers are not expected to have a significant influence in this class, since the FDA will not approve generics in CFC-containing inhalers.

## ANTI-ASTHMATICS

**RANK 7**

## COMPONENTS OF TREND

Cost per Prescription	14.4%
Inflation	7.6%
Units per Prescription	0.4%
Brand/Generics Mix	-0.2%
Therapeutic Mix	6.1%
9.9%	
Realization	
Prevalence	10.4%
Intensity	-0.5%
New Drugs	0.4%
TOTAL	26.1%

## KEY FACTS

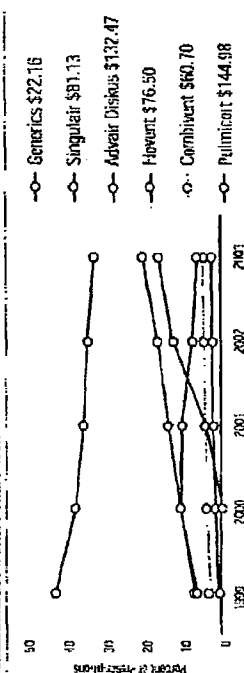
TAMPY: \$28.20  
 Rx PMPY: 0.41  
 Prevalence of Use: 7.5%  
 Average Cost/Rx: \$69.67  
 # Rx/User/Year: 5.36

Antiasthmatic drugs had an overall increase in trend of 26.1%, up about 24% from 2002. The primary reasons were growth in utilization, which rose from a modest 2.6% in 2002 to 9.9% in 2003, and an increase in asthma prevalence of 10.4%. Cost per prescription for this class continued to grow at double-digit rates due to use of more expensive controller products.

Generic products, led by albuterol, continued to dominate the market share for antiasthmatics, but the gap is closing. In 1999, generics held 42.7% of the market, but in 2003 that number fell to 32.9%. Newer drugs, such as Advair Diskus<sup>2</sup> and Singulair<sup>®</sup>, have gained share during that time, and those products now represent about 37% of total prescriptions.

As expected, Flovent® share continues to decline as patients are switched to Advair. It is also important to note that the average cost per prescription for Advair is less than the combined price of its individual components (Flovent and Serenent<sup>®</sup>) used separately.

### Antiaesthetics Market-Share Trend



89 express scripts

## THERAPY CLASS REVIEW

## PATENT EXPIRATIONS

Brand	Generic	Manufacturer	Patent Expiration
Glucovance <sup>®</sup>	metformin/glibenclamide	Roche-Myers Squibb	Jan. 31, 2004
Avandia <sup>®</sup>	rosiglitazone	GlaxoSmithKline	Oct. 6, 2005

The antidiabetic category is very active, with a mixture of new, old and reformulated products.

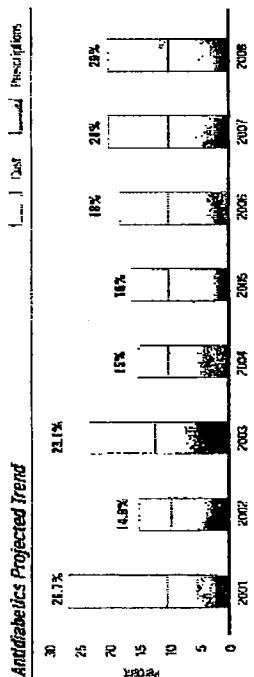
Several new insulin products are in active development, including a rapid-acting insulin, a long-acting insulin and an inhaled insulin. Apidra, the new rapid-acting insulin, was approved in April 2004. It will compete with Humalog and Novolog<sup>®</sup>. Two long-acting products, Basulin and insulin detemir, may compete with Lantus. Although the inhaled insulin product Exubera has been delayed from its initial projections, its development continues to progress. Additional trials have recently been completed to potentially support its re-submission for FDA review. Although Symlin and exenatide are not insulins, they are in development to be given by subcutaneous injection (similar to insulin) to aid in better control of blood sugar levels. The first agent in the new therapy class called amylin receptor agonists or amylinomimetic agents; Symlin is a synthetic form of the natural hormone, amylin. Exenatide also belongs to a new therapy class, increlin mimetic agents.

In general, the development of oral antidiabetic agents can be divided into two groups. The first group includes drugs that affect peroxisome proliferator-activated receptors (PPAR). These drugs, often referred to as glitazones, work by sensitizing the body to insulin. These products in development include rosiglitazone, tesaglitazar and mureglitazar. Since they can also affect the PPAR receptors in different ways, some may demonstrate a beneficial effect on blood cholesterol levels. The second area of development includes drugs that affect the enzyme dipeptidyl peptidase IV (DPP-IV). Therapy with these drugs would raise a protein called glucagon-like peptide-1, resulting in control of blood sugar only when it is too high. As a result, the risk of hypoglycemia (abnormally low blood sugar levels) would decrease. MK-0431 and LA-237 are two such drugs under study.

Complications associated with diabetes are also receiving increased attention, with a number of products being examined for their effects on neuropathic pain, retinopathy (retinal disease) and nephropathy (kidney disease) related to diabetes. Lyrica, the furthest advanced in development, is the follow-on to Neurontin<sup>®</sup>. A second product in development is riboketarin, which blocks the effects of PKC, an enzyme that has been implicated in the underlying process of microvascular complications (diabetic retinopathy, peripheral neuropathy and nephropathy).

## Looking Ahead

Several leading products, representing 22% of 2003 market share, will become available as generics in 2004, which is likely to drive overall trend lower than in 2003. However, the increasing prevalence of obesity and a continuing emphasis on aggressive management of diabetes will keep utilization rates high. We project an overall unmanaged trend of 15% for 2004, rising to 20% by 2007-2008.



## PIPELINE — ORAL ANTIDIABETICS

Brand	Generic	Company	Proposed Use	Availability
Avandia <sup>®</sup>	rosiglitazone/glibenclamide	GlaxoSmithKline	Oral antidiabetic	2004
Galvus <sup>®</sup>	basaglitazone	Novo Nordisk	Oral antidiabetic	2006
	mureglitazar	Bristol-Myers Squibb	Oral antidiabetic	2006
	tesaglitazar	AstraZeneca	Oral antidiabetic	2007
	MK-0431	Merck	Oral antidiabetic	2007
	linagliptin	Novo Nordisk	Diabetes (Type 2)	2007
	LA-237	Noventis	Oral antidiabetic	2007
	peglutared	Isordia	Oral antidiabetic	Unknown
	mudformin			

## PIPELINE — INSULINS

Brand	Generic	Company	Proposed Use	Availability
	insulin detemir	Novo Nordisk	Long-acting insulin	2004
Synlin <sup>®</sup>	exenatide	Amgen/Novartis	Diabetes (Type 2)	2004
	pramlintide	Amgen	Diabetes	2005
Exubera <sup>®</sup>	Inhaled insulin	Pfizer/Novartis	Diabetes (Types 1 and 2)	2006
Basulin <sup>®</sup>	basal insulin	Bristol-Myers Squibb/Flarex	Long-acting insulin	2007+

## PIPELINE — AGENTS FOR DIABETES COMPLICATIONS

Brand	Generic	Company	Proposed Use	Availability
Lyrica <sup>®</sup>	pregabalin	Pfizer	Neuropathic pain	2004
	riboketarin	Novartis	Diabetic complications	2006
Pyridium <sup>®</sup>	pyridostigmine	Novartis	Diabetic neuropathy	2006
Neuroderm <sup>®</sup>	pyridostigmine	Novartis	Diabetic neuropathy	2007
	pyridostigmine	Novartis	Diabetic neuropathy	2007
	pyridostigmine	Novartis	Diabetic neuropathy	2007

56 express scripts

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## THERAPY CLASS REVIEW

## ANTI-DIABETICS

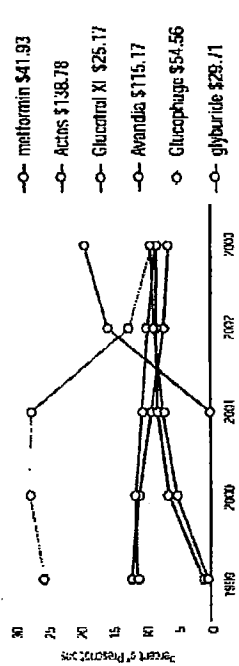
## RANK 6

COMPONENTS OF TREND		KEY FACTS
Cost per Prescription	10.2%	PMPY: \$31.66
Inflation	7.4%	Rx PMPY: 0.40
Units per Prescription	0.6%	
Brand/Generic Mix	-1.2%	Prevalence of Use: 3.6%
Therapeutic Mix	3.3%	Average Cost/Rx: \$64.40
Utilization	11.7%	# Rx/Use/Year: 13.12
Prevalence	10.4%	
Intensity	1.2%	
New Drugs	0	
TOTAL	23.1%	

Antidiabetics saw an increase in overall drug trend from 14.5% in 2002 to 23.1% in 2003. Costs per prescription and utilization growth, particularly an increase in prevalence, contributed about equally to the overall increase. The prevalence of Type 2 diabetes has reached nearly epidemic magnitude in the United States, with more new patients taking oral agents and insulin. Costs due to brand/generic mix returned to near-normal levels in 2003, after dropping significantly in 2002 due to the Glucophage® patent expiration. Inflation rose as well, with many of the newer insulin products showing the largest gains.

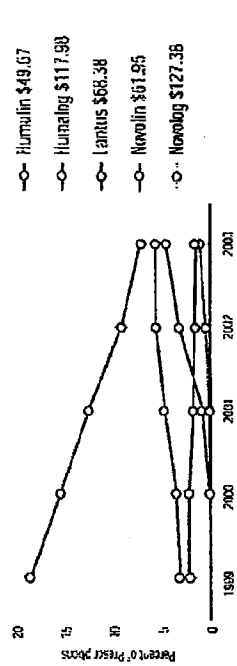
Metformin continued to be the market-share leader. Other oral drugs, Actos® and Avandia®, showed mixed results. Actos grew in market share to 9.2%, but Avandia share decreased by 0.1% to 8.2%. If the newer product Avandamet™ (a combination of metformin and Avandia), which had a 1% share in 2003, is included, the Avandia family of products also had a 9.2% share in 2003. These products continued to outpace the rest of the oral antidiabetic class in terms of average cost per prescription, with Actos at 2.2 times the average cost of the class, and Avandia at 1.8 times the class average.

Oral Antidiabetics Market Share Trend



Among insulins, the Humulin® family of products remained the market leader, with 6.7% of the market share in 2003. However, Humulin's share of the market has fallen by about 40% in the last two years, as newer products, such as Humalog® and Lantus®, increase their presence in the market. These newer products cost about twice as much as their predecessors.

Insulin Market Share Trend



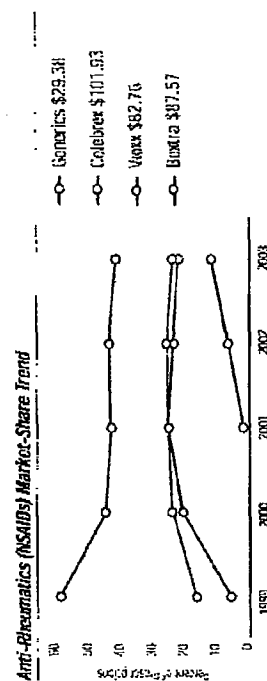
## THERAPY CLASS REVIEW

## ANTI-RHEUMATICS (NSAIDs) RANK 5

COMPONENTS OF TREND		KEY FACTS
Cost per Prescription	12.7%	PMPY: \$34.95
Inflation	5.8%	Rx PMPY: 0.43
Units per Prescription	0	
Brand/Generic Mix	0.3%	
Therapeutic Mix	6.8%	
Utilization	5.6%	
Prevalence	1.0%	Prevalence of Use: 12.3%
Intensity	4.5%	Average Cost/Rx: \$82.04
New Drugs	3.2%	# Rx/User/Year: 3.47
TOTAL	22.2%	

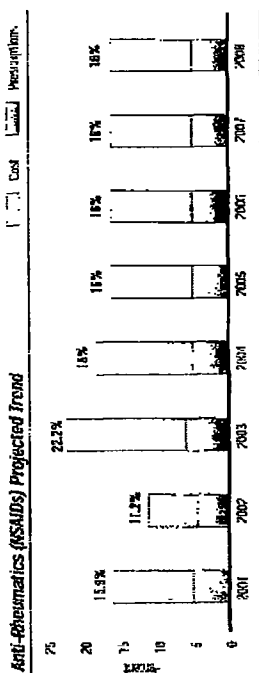
The anti-rheumatic therapy class consists of non-steroidal anti-inflammatory drugs (NSAIDs), COX 2 inhibitors (COX-2s) and injectable drugs for rheumatoid arthritis (RA). Drug trend growth in this class ran contrary to most of the other top classes, with relatively low increases in utilization offset by higher than average increases in cost per prescription. Utilization growth has averaged approximately 5% over the past three years, due to a stable mix of both products and patients, no new indications of significance and a high penetration rate. The COX-2s Celebrex®, Vioxx® and Bextra® grow in combined market share from 50.6% in 2002 to 53.1% in 2003. New drugs also contributed 3.2% to overall trend, with the most significant one being Humira®, a new injectable drug for RA that was approved on the last day of 2002. Overall, the injectable drugs Humira and Enbrel® contributed \$7.24, or approximately 1.1% of total PMPY spent in 2003.

Despite the introduction of a new product, Bextra, in 2001, generic market share has held constant in the 40% range for the past four years. Partly attributable to the slower growth rates mentioned above, the high generic use is also due to utilization management strategies, such as step therapy, that require first-line use of a generic product. Among the COX-2s, Celebrex remained the market leader, with a 22.4% share.



52 express scripts

**Looking Ahead**  
While the possible entry of a fourth COX-2, Arcoxia™, in 2004 may increase the already significant direct-to-consumer (DTC) advertising in this class, Arcoxia's possible impact on overall utilization is not as clear. Although Arcoxia is likely to take market share from the other COX-2 inhibitors, its overall impact on drug trend should be negligible. Without active management, continued growth of Enbrel and Humira, and the resultant increases in the average cost per prescription will drive trend, which should level off at about 16% annually after 2004.



PIPELINE	Brand	Generic	Company	Proposed Use	Availability
	Arcoxia™	celecoxib	Merck	Osteoarthritis (OA)/RA/Pain	2004
	Dynastat®	parecoxib injectable	Pfizer	Acute pain	2005
	Humira®	CTLA4-Ig injectable	Abbvott	RA	2006
	Enbrel®	etanercept	Amgen	RA	2006
	Arcoxia™	celecoxib	Merck	Acute and chronic pain	2006
	Humira®	CTLA4-Ig injectable	Abbvott	Multiple sclerosis	2006
	Enbrel®	etanercept	Amgen	Fibromyalgia	2007
	Arcoxia™	celecoxib	Merck	RA	2007

PATENT EXPIRATIONS	Brand	Generic	Manufacturer	Patent Expiration
	Humira®	etanercept	Abbvott	April 13, 2006

Prescriptions in this broad category will continue to be dominated by the COX-2s. By 2006, seven COX-2s are expected to be on the market, including the first injectable product. In upcoming years, an increasing amount of drug spending will shift to injectable products. Drugs already on the market, such as Enbrel, Remicade® and Humira, will be joined by CDP-810 and CTLA4-Ig in the increasingly crowded RA market. Humira, a common yet difficult to treat disease, may see its first FDA-approved treatment later this decade. Patent exposure in this class is limited, as the COX-2s have many years of patent protection remaining and the biotechnology products are not subject to generic competition under current FDA regulations.

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## THERAPY CLASS REVIEW

## ANTIHYPERTENSIVES

RANK 4

## COMPONENTS OF TREND

Cost per Prescription	4.0%
Inflation	6.3%
Units per Prescription	0.3%
Brand/Generic Mix	-5.1%
Therapeutic Mix	2.7%
Utilization	12.4%
Prevalence	10.7%
Intensity	1.5%
New Drugs	0
TOTAL	16.9%

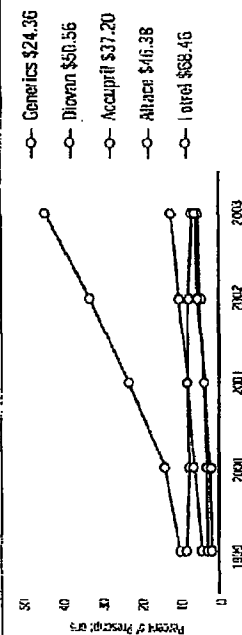
## KEY FACTS

PMPY: \$36.15
Rx PMPY: 0.96
Prevalence of Use: 9.1%
Average Cost/Rx: \$37.51
# Rx/User/Year: 9.94

The antihypertensive class, which consists mainly of angiotensin-converting enzyme inhibitors (ACEIs), angiotensin receptor blockers (ARBs), vasodilators and combination products, continued to be the most widely prescribed therapy class in 2003, at 0.96 prescriptions PMPY. The rate of utilization increased in 2003 to 12.4%, up from 10.6% in 2002. Double-digit increases in utilization have been the norm in recent years, likely due to both the aging of the population and more aggressive treatment of hypertension. Generics are still having a significant impact, as the brand/generic mix of -5.1% helped keep the cost per prescription increase low at 4%.

Generics for ACEIs are taking a bigger and bigger piece of the market share in this class. Approximately 44% of 2003 prescriptions were for generic drugs, and drugs that account for another 10% of prescriptions are scheduled to lose patent protection in 2004. The ARB class has been affected by generic ACEIs, as only one family of ARB products (Diovan<sup>®</sup> and Diovan<sup>®</sup> HCT) reached a market share of greater than 10%.

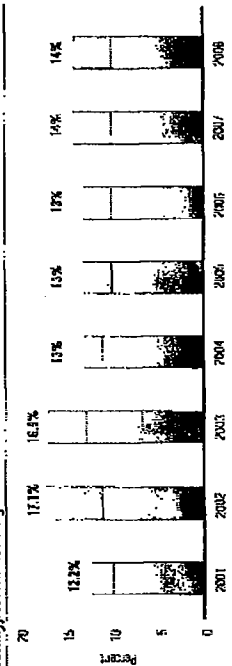
Antihypertensives Market-Share Trend



## Looking Ahead

As stated previously, the additional generics expected in 2004 should result in even more price pressures and should keep cost-per-prescription growth modest. Utilization growth should continue. Unless the class is managed actively, we expect a similar increase in trend going forward, at around 13%-14% annually.

## Antihypertensives Projected Trend



## PIPELINE

Brand	Generic	Company	Proposed Use	Availability
	aliskiren	Novartis	Hypertension	2006
	amlodipine	Myogen	Pulmonary hypertension	2006
	sildenafil	Erosive	Pulmonary hypertension	2006
	duloxetine	Bayer	Resistant hypertension	2007+

## PATENT EXPIRATIONS

Brand	Generic	Manufacturer	Patent Expiration
Accupril <sup>®</sup>	quinapril	Pfizer	Pending
telmisartan <sup>®</sup>	telmisartan	Novartis	Feb. 11, 2004
Altace <sup>®</sup>	ramipril	King	July 27, 2005
Accutol <sup>®</sup>	perindopril	Schering	Oct. 3, 2007

Traditionally, this class of compounds has contained ACEIs and ARBs. The ACEI class has reached maturity, with several generics now available. The ARB market, while not yet mature, has no new products in development, and future growth is tied either to new indications, such as congestive heart failure, or to conversions from other antihypertensive classes. The pipeline drug aliskiren represents the first in a new class of compounds called renin inhibitors. Renin is an enzyme in the kidney that causes the production of angiotensin I, which contributes to increased blood pressure. Aliskiren prevents the activity of renin much like an ACEI prevents the activity of angiotensin-converting enzyme. The pipeline drugs enbrisentan and sitasentan are for the treatment of pulmonary hypertension, a rare but more severe type of hypertension.



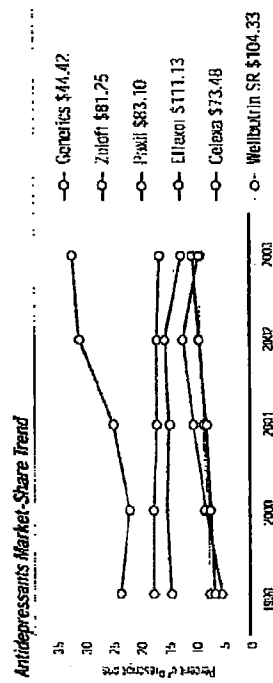
## ANTIDEPRESSANTS

### **RANK 3**

COMPONENTS OF TREND		KEY FACTS	
Cost per Prescription	5.1%	PMPV: \$58.92	
Inflation	6.7%	Rx PMPV: 0.80	
Units per Prescription	0.1%	Prevalence of Use: 10.4%	
Brand/Generic Mix	-2.1%	Average Cost/Rx: \$73.36	
Therapeutic Mix	1.1%	# Rx/User/Year: 7.7	
Utilization	11.2%		
Prevalence	6.6%		
Intensity	4.2%		
New Drugs	0		
TOTAL	16.9%		

Antidepressants remained one of the more dynamic therapy classes in 2003. Overall trend was down from 2002, at 16.9% versus 18.7%. Driving this decrease was a slowing in utilization growth of about 4 percentage points, from 15.6% to 11.2%. The absence of new treatment guidelines, new indications and significant new drug classes all likely contributed to the slowdown. Offsetting the decline in utilization growth was an increase (from -5.1% to -2.1%) in brand/generic mix, as new products like Lexapro<sup>TM</sup> and Paxil CR<sup>TM</sup> counteracted the patent expirations of Prozac<sup>®</sup> and Paxil<sup>®</sup>.

Lexapro gained the most market share of any new antidepressant in 2003, rising from 0.7% to 7.5% of prescriptions. Celexa™, an older product from the same manufacturer, bore the brunt of the Lexapro gain, dropping from 11.9% to 9%. Celexa's share is expected to drop even further as marketing efforts have ceased in anticipation of generic competition in late 2004 or early 2005. Wellbutrin SR® is another product exposed to generic competition, but the successor product, Wellbutrin XL™ (introduced in 2003), may preserve market share for that franchise.

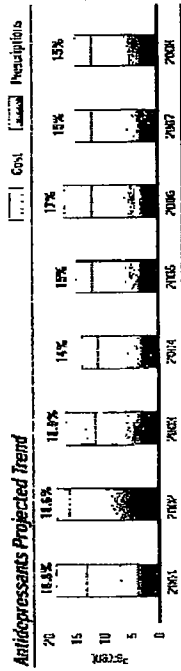


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## THEORY CLASS REVIEW

## Looking Ahead

The probable approval of a non-selective serotonin reuptake inhibitor (SSRI), Cymbalta™, in 2004 is expected to increase competition in the antidepressant class, but it may also lead to further market consolidation. As mono SSRIs become available as generics, a movement to non-SSRIs is taking place in the market, with two non-SSRIs, Effexor® and Wellbutrin SR, among the top five antidepressants in market share. It is also worth noting that the AWP per prescription for either Effexor or Wellbutrin (including their sustained-release forms) is about \$20 per prescription higher than the branded SSRIs and up to \$40 higher than the generic SSRIs. Given these facts, we project annual increases in the 15% range for antidepressant spend if not actively managed.



**जम्हाती**

Brand	Generic	Company	Proposed Use	Availability
Cymbalta <sup>®</sup>	citalopram	Lilly	Depression	2004
Lexapro <sup>®</sup>	escitalopram	Schering/Wellcome	Depression	2004
Wellbutrin <sup>®</sup>	bupropion	Organon	Depression	2005
Variza <sup>®</sup>	SR-56511	Schering-Plough	Depression	2006
	R-673	Radiant	Depression/ Anxiety disorder	2007
	397102	GlaxoSmithKline	Depression	2007
	DVS-233	Wyeth	Depression	2007*
	mefenazine	Concept	Psychiatric major depression	Unknown

**PALM EXPIRATIONS**

Brand	Generic	Manufacturer	Patent Expiration
Cibac <sup>®</sup>	clonidine	Forest	Jan. 17, 2004*
Wellbutrin SR <sup>®</sup> /Zola <sup>®</sup>	clonidine SR	GlaxoSmithKline	Pending
Wellbutrin XL <sup>®</sup>	clonidine XL	Pfizer	Mar. 20, 2006
Wellbutrin SR	clonidine SR	GlaxoSmithKline	Aug. 28, 2006
Prin <sup>®</sup>	prazosin	GlaxoSmithKline	June 29, 2017***
Librium/SR	alprazolam	Wegert	Aug. 13, 2009

DATE	TIME	LOCATION	REMARKS
11/11/2005	18:00	1500m	1500m survey (available)
11/11/2005	18:00	1500m	1500m survey (available)

The significant new drug story in the near future is Cymbalta, with approval expected in 2004. Cymbalta will compete with a similar drug, Effexor. The active ingredient in Cymbalta, duloxetine, is also being studied for urinary incontinence. A highly studied new category of antidepressants, the norepinephrine receptor antagonists, has not shown success to date, but several products are still in active development, including R-673 from Roche. Looking ahead, successor products to Wellbutrin XL (333-3162) and Effexor XR (DVS-223) are in early stages of research. Patient expirations will continue to loom large in this category, with several significant drugs set to lose their patents in upcoming years.

## GASTROINTESTINALS

## RANK 2

## COMPONENTS OF TREND

Cost per Prescription	-0.5%
Inflation	4.0%
Units per Prescription	0.7%
Brand/Generic Mix	-1.4%
Therapeutic Mix	2.7%
Utilization	12.0%
Prevalence	6.8%
Intensity	4.8%
New Drugs	0
<b>TOTAL</b>	<b>11.5%</b>

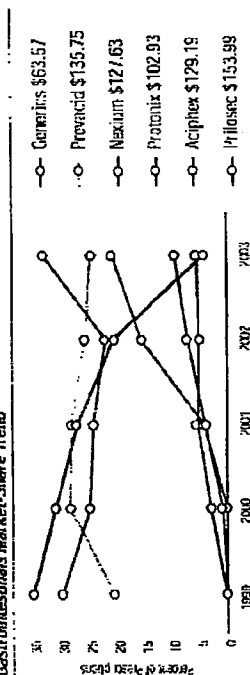
## KEY FACTS

PMPY: \$38.56  
 Rx PMPY: 0.56  
 Prevalence of Use: 8.8%  
 Average Cost/Rx: \$106.28  
 # Rx/User/Year: 6.35

PMPY trend for gastrointestinal drugs dropped significantly in 2003, yet the class managed to maintain second place in terms of PMPY spend. The patent expiration of Prilosec<sup>®</sup>, the subsequent availability of generics and the launch of Prilosec OTC<sup>®</sup> all contributed to this decrease. But other factors came into play as well. Inflation dropped to 4% in 2003, from 8.7% in 2002, as the generic product gained market share but did not increase prices significantly. Utilization growth slowed but still remained in double digits. The different clinical indications for the OTC versus the prescription versions resulted in little conversion of prescription users to OTC.

In terms of market share, Prevacid<sup>®</sup> continued to lead branded products, but for the first time in many years generics topped market share at 33.1%. Nexium<sup>®</sup> and Protonix<sup>®</sup> continued to grow from a combined share of only 8.2% in 2001 to a 30.1% share in 2003. As expected, Prilosec's share dropped quickly after generics entered the market, but the overall market share for the omeprazole franchise, brand and generic, also declined due to the high cost of omeprazole generics, continued marketing of the brand manufacturers and, to a lesser extent, Prilosec OTC.

## Gastrointestinals Market Share Trend



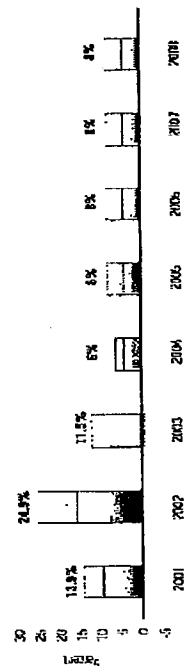
45 express scripts

## THERAPY CLASS REVIEW

## Looking Ahead

With no patent expirations looming and additional OTC products uncertain, the group of products in this class should not change significantly in the coming years. We predict a slowing of PMPY growth to 6% in 2004 due to lower generic prices, and then a rebound to approximately 8% annually from 2005 to 2008, absent any active management of the therapy class.

## Gastrointestinals Projected Trend



## PIPELINE

Brand	Generic	Company	Proposed Use	Availability
Enalapril	perindopril	Amgen	Mucositis	2005
Enalapril	lurasidone	Genzyme	Clostridium difficile-associated diarrhea	2005
Enalapril	clonidine	Solvay	Intestinal bowel syndrome	2005
Enalapril	abiraterone	Actavis	Post-operative ileus	2006
Enalapril	COP-870	Celtech	Orbital disease	2006
Enalapril	flutamide	Abbott	Dyslipidemia	2007
Enalapril	telaprevir	NPS	Short bowel syndrome	2007
Enalapril	ritonavir	Wyeth	Crohn's disease	2007
Enalapril	mesalazine	Amgen	GERD	2007
Enalapril	telaprevir	Amgen	Intestinal bowel syndrome	2007

## PATENT EXPIRATIONS

Brand	Generic	Manufacturer	Patent Expiration
Diphenhydramine	gabapentin	Pfizer	Jan. 31, 2005
Enalapril	gabapentin	GlaxoSmithKline	July 25, 2005
Enalapril	gabapentin	Pfizer	June 29, 2005

New drug development appears to be moving away from peptic ulcer disease and gastroesophageal reflux disease (GERD), two disorders that dominated sales in this category over the past 20 years. Currently available proton pump inhibitors (PPIs), with the exception of Prilosec<sup>®</sup>, will likely retain patent protection for the remainder of the decade. Now that Prilosec OTC<sup>®</sup> is approved, the possibility that other PPIs could become available as OTC products in the coming years could decrease the rate of growth of the remaining prescription products. Omeprazole's disease and irritable bowel syndrome appear to be areas of increased focus, with several drugs in development. Another area of research involves finding a successor to Propulsid<sup>®</sup>, a drug commonly used for gastroprotection, ileus and GERD before its withdrawal from the market in 2000 due to cardiac side effects.

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## THEORY CLASS REVIEW

## RANK 1

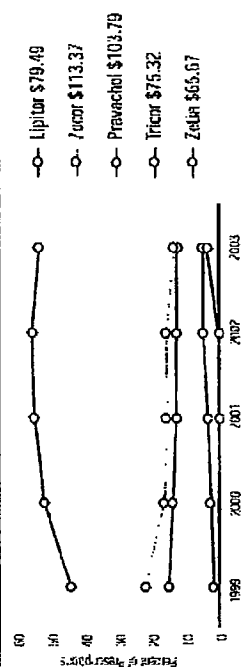
## ANTIHYPERLIPIDEMICS

COMPONENTS OF TREND		KEY FACTS	
Cost per Prescription	5.2%	PMPY: \$64.11	
Inflation	6.1%	Rx PMPY: 0.77	
Units per Prescription	-0.5%		
Brand/Generic Mix	0		
Therapeutic Mix	-0.3%	Prevalence of Use: 8.4%	
Utilization	17.4%	Average Cost/Rx: \$83.62	
Prevalence	13.2%	# Rx/User/Year: 9.15	
Intensity	3.6%		
New Drugs	0.3%		
TOTAL	23.8%		

In 2003, the antihyperlipidemics class passed the gastrointestinal drugs to take over as the top therapy class, with a PMPY cost of \$64.11. Utilization continued to drive antihyperlipidemic drug trend, rising 17.4% in 2003. Approximately 75% of this increase was attributable to a growing number of people taking these medications. Prevalence grew by 13.2% to 7.6 per 1000 members. Increased awareness of recently updated cholesterol guidelines likely drove these utilization gains.

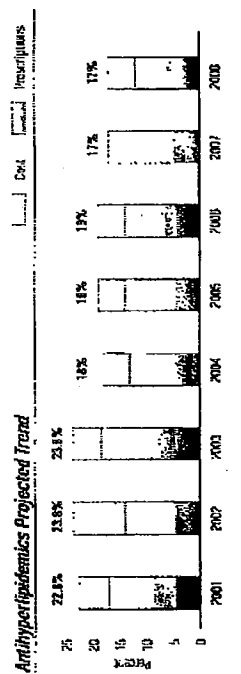
Statins continued to dominate the therapy class, but a new entrant, "Zetia," made inroads during 2003, gaining a 3.7% market share. Zetia, which was approved in late 2002, works by a different mechanism than the statins. It took market share largely from Lipitor<sup>®</sup> and Zocor<sup>®</sup>. In 2003, the first generic statin, lovastatin, also grew in market share — from 1% to 1.7% of prescriptions. The newest statin, Crestor<sup>®</sup>, was approved in the second half of 2003, but it did not reach a significant market share by the end of the year.

## Antihypertensive Market-Share Trend



## Looking Ahead

The recent release of the PROVE-IT study, which showed that aggressive lowering of LDL cholesterol resulted in fewer cardiovascular events, may result in changes to treatment guidelines that call for even greater reductions in LDL, which in turn could cause utilization to remain high. In addition, the introduction of at least one significant new product in 2004, increased marketing of the statins, and the aging of the population will result in continued growth that keeps antihyperlipidemics near the top of all therapy classes. We expect strong trend for the class to average 18% over the next four years.



PIPELINE					
Brand	Generic	Company	Proposed Use	Availability	
Viread®	tenofovir disoproxil fumarate	Mylan-Schering-Plough	Cholesterol-lowering	2004	
Lipitor/morpherapla	rosuvastatin/calcium rapsorb	Pfizer	CYP inhibitor	2006	
	FIC-276	Pfizer	HDL induction	2007	
	IT-705	Regan Tobacco	CYP inhibitor	2007+	
Nevocon® OTC	lovastatin	Merck	OTC	Unknown	
Provenor® OTC	pravastatin	Bristol-Myers Squibb	OTC	Unknown	

PATENT EXPIRATIONS			
Brand	Generic	Manufacturer	Patent Expiration
Pravachol	pravastatin	Bristol-Myers Squibb	April 20, 2006
Zenon	simvastatin	Merck	June 23, 2006

As statins approach the end of their life cycle, manufacturers are trying new ways to protect and extend their franchises. Combination products, such as Vytorin and Caduet<sup>®</sup> (approved in January 2004), which combines the antihypertensive Norvasc<sup>®</sup> with Lipitor, are one such strategy. If they are successful, combination statin therapies will reduce the cost-saving opportunities from the patent expirations that begin in 2006. Pharmaceutical manufacturers are also developing new OTC statins, with both Mevacor and Pravastatin currently under review by the FDA for OTC status. In new drug development, the focus is shifting to products that increase HDL, or "good" cholesterol, rather than decreasing LDL, or "bad" cholesterol. Both oral and injectable products that raise HDL are being developed, with the first oral product, a cholesterol ester transfer protein (CETP) inhibitor combined with the statin Lipitor, likely to reach the market in 2006.

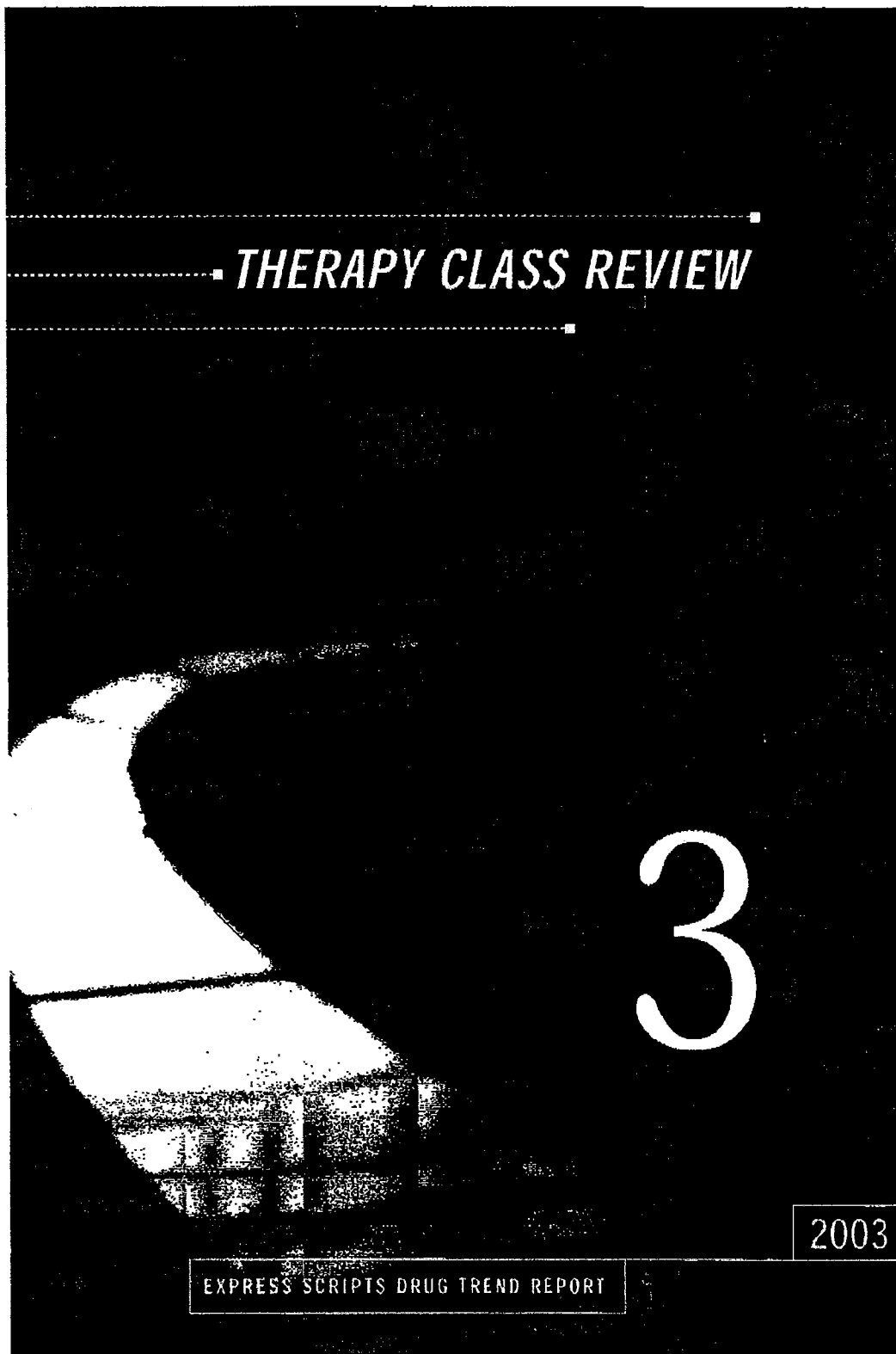


## Therapy Class Review

In this section, information on the utilization and cost of the top 25 therapy classes for 2003 is presented. For the first time, components of trend have been detailed for each class. Also included are market-share trends for the major drugs within the class and projected trends for the class as a whole. All drugs classified in this Report as both Common and New are included in the reviews. Drugs that are in the pipeline and patent expirations that have significant potential to affect a specific class in the next several years are also presented. For each therapy class, adding the percentage contributions of each factor does not equal the total percentage increase. The calculation takes the base cost for a given year and multiplies it by one times the percentage contributed by the first factor (inflation). The resulting total is then multiplied by the percentage contributed by the second factor (number of units dispensed) and so on for each Common Drug factor. The percentage contribution of the New Drugs is then added to the total Common Drug percentage to yield a total percentage increase. The final results may differ due to rounding.

Unmanaged, Non-Discounted Cost per Prescription and PMPY Cost  
For the Top 25 Therapy Classes 2002 to 2003 (Including Specialty Drugs)

Therapy Class	AWP per Rx			PMPY Cost		
	2002	2003	% Change	2002	2003	% Change
Ant hyperlipidemics	\$79.52	\$83.62	5.2%	\$51.78	\$64.11	23.8%
Gastrointestinals	\$106.76	\$106.28	-0.5%	\$53.42	\$69.66	11.5%
Antidepressants	\$69.77	\$73.36	5.1%	\$50.41	\$56.92	16.9%
Antihypertensives	\$36.08	\$37.51	4.0%	\$30.93	\$36.15	16.9%
Anti-Rheumatics (NSAIDs)	\$71.03	\$82.04	15.5%	\$28.61	\$34.95	22.2%
Antidiabetics	\$58.41	\$64.40	10.2%	\$25.71	\$31.66	23.1%
Ant asthmatics	\$60.71	\$69.67	14.8%	\$22.35	\$28.20	26.1%
Misc Endocrines	\$83.68	\$87.74	4.1%	\$14.97	\$19.03	27.1%
Narcotic Analgesics	\$32.26	\$37.45	16.1%	\$14.99	\$18.70	24.7%
Anticonvulsants	\$82.66	\$93.91	13.6%	\$14.22	\$18.33	28.9%
Antivirals	\$246.84	\$243.79	-1.2%	\$15.85	\$17.69	11.6%
Dermatologicals	\$48.84	\$55.34	13.0%	\$15.19	\$17.13	12.8%
Antihistamines	\$58.97	\$54.66	-7.3%	\$21.62	\$17.11	-20.9%
Calcium Blockers	\$43.70	\$44.56	2.0%	\$13.70	\$14.21	3.7%
Beta Blockers	\$24.54	\$26.90	9.6%	\$10.43	\$13.01	24.7%
Oral Contraceptives	\$26.44	\$27.14	2.6%	\$10.66	\$12.27	15.1%
Misc. CNS Agents	\$332.01	\$377.25	13.6%	\$8.63	\$11.04	27.9%
Antineoplastics	\$184.12	\$182.02	-4.3%	\$8.95	\$10.31	15.2%
Decongestants	\$54.39	\$59.13	8.7%	\$8.36	\$9.69	15.9%
Quinolones	\$77.70	\$84.20	8.4%	\$7.74	\$8.94	15.4%
Antipsychotics	\$116.47	\$137.69	18.2%	\$6.90	\$8.89	28.8%
Migraine Products	\$132.63	\$139.12	4.9%	\$8.26	\$8.77	6.2%
Stimulants/Anti-Obesity	\$68.55	\$83.84	22.3%	\$6.16	\$8.76	42.2%
Macrolides	\$41.42	\$44.10	6.5%	\$7.46	\$8.74	17.1%
Estrogens	\$25.18	\$27.47	9.1%	\$10.95	\$8.41	-23.2%
Top 25	\$60.26	\$65.26	8.3%	\$468.28	\$544.59	16.3%
Other	\$33.09	\$35.03	5.9%	\$117.18	\$131.91	12.6%
Total	\$51.76	\$55.86	7.9%	\$585.46	\$676.50	15.5%





*Notes*

42 express scripts

## SPECIALTY DRUGS

As shown in Exhibit 17, increased utilization was the principal reason for the nearly 40% growth in spending for specialty drugs in 2003. While spending slowed in 2003 on a percentage basis, the dollar increase in the last two years has been nearly \$10 PMPM. However, the increase in specialty drug spend is due primarily to the transfer of specialty prescription management to the pharmacy benefit and away from the medical benefit, rather than to radically increased use of these drugs. For this reason, Exhibit 9 on page 26 shows 2002 to 2003 trend both including and excluding specialty products.

## Specialty Drug Trend 2001 to 2003

Year	PMMP RIS	Trend	Avg Cost per Rx	Trend	PMMP Cost	Trend
2001	0.014	N/A	\$1,081.40	N/A	\$15.44	N/A
2002	0.020	44.5%	\$1,193.90	9.4%	\$24.42	58.1%
2003	0.028	35.3%	\$1,223.59	2.5%	\$33.87	38.7%

The PMMP cost of \$33.87 shown in Exhibit 17 reflects only a relatively small percentage of the actual overall cost of specialty drugs to plan sponsors. Express Scripts' subsidiary, CumScript, estimates that approximately 70% of specialty drug spend is still included in the medical benefit. Increasingly, however, plans are carving specialty drugs out of the medical benefit, so their costs can be managed better through more effective price negotiation as part of the pharmacy benefit.

The top five specialty drugs for the 2003 drug trend population sample are shown in Exhibit 18. Each of the top five drugs has at least one competing product that has comparable, if not identical, clinical results. Additionally, the FDA is investigating ways to change the current expensive and time-consuming approval process for generic biotechnology drugs. Increased development of new products and generic equivalents for established products will help somewhat in moderating cost growth in future years.

40 express scripts

## Top Five Specialty Drugs 2003

Brand Name (Approval Date)	Indication	PMMP Cost	Main Competitor(s) (Approval Date)
Enbrel® (1998)	Rheumatoid Arthritis	\$5.40	Humira® (2002)
Rebetol® (2001)*	Hepatitis C	\$2.60	COPEGUS® (2002) Ribasphere® (2004) ribavirin (2004)
Copaxone® (1997)	Multiple Sclerosis	\$2.37	Bonivon® (1993) Avomet® (1996) Rebit® (2007)
PEG-Intron® (2001)	Hepatitis C	\$2.08	Pegasys® (2002)
Procrit® (1990)	Anemia	\$1.70	Eprex® (1999) Aranesp® (2001)
Other		\$16.11	
Total		\$33.87	

\* Alimant Inc. has been approved since 1999 as part of the combination product Rebetol®. It was not approved by the FDA as a separate drug until 2001. Costs were rounded in 2004.

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In 2003, the influence of new drugs accounted for a relatively modest 0.7% increase: — 0.3% in utilization and 0.4% in cost. As shown in Exhibit 16, only 10 of the top 25 therapy classes had a measurable change due to new drugs. In half of these 10 classes, greater change was due to high cost of the new drugs relative to other drugs in the class. In the remaining five classes, the utilization of the new drugs exceeded their cost-per-prescription impact. Only two of the 10 classes actually decreased in per-prescription cost due to the introduction of new drugs.

The stimulants/anti-obesity class exhibited by far the largest growth in spend due to new drugs. This growth was driven by *Similtra*®. Although it is not a stimulant, *Similtra* is included in the class because it is indicated for the treatment of attention deficit/hyperactivity disorder (ADHD). Other ADHD treatments and anti-obesity drugs are stimulants. Despite having comparable efficacy to currently available treatments, *Similtra*'s dramatic uptake was fueled by being the first non-norecotic treatment for ADHD and by the heavy use of direct-to-consumer advertising to promote the product.

In 2003, 21 new molecular entities and 22 new biologic agents were approved by the FDA.<sup>13</sup> This substantial increase over the previous year's approvals may be due to the steps taken by the FDA to shorten the new drug review process. It should be noted that two of the new products, Relpax<sup>®</sup> and Crestor<sup>®</sup>, actually reduced costs in their respective therapy classes (migraine products and gastrointestinal) because they were introduced at lower costs than already established drugs in their classes.

13 FDA says rebound in approval of innovative drugs in 2003 tied innovative pathway, facilitated in speed approvals in years ahead. *Issues released*, Washington, DC: US Food and Drug Administration; January 15, 2004.

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**Changes in New Drugs per Prescription for the Top 25 Therapy Classes 2002 to 2003  
Ranked by Percent Change**

Rank	Therapy Class	Significant New Drugs	% Initiation	% Cost	% Change
1.	Stimulants/Anxi-Obesity	Strattera <sup>®</sup>	15.5%	5.5%	21.0%
2.	Antineoplastics	Immun <sup>®</sup>	0.4%	4.2%	4.7%
3.	Anti-Rheumatics (NSAIDs)	Humira <sup>™</sup>	0.2%	3.0%	3.2%
4.	Misc. Endocrinies	Forxiga <sup>®</sup> , Somavert <sup>®</sup>	0.3%	1.9%	2.1%
5.	Migraine Products	Relpax <sup>®</sup>	1.9%	0.1%	1.8%
6.	Antivirals	Reyata <sup>™</sup>	0.3%	0.5%	0.8%
7.	Dermatologics	Finacea <sup>™</sup>	0.3%	0.1%	0.5%
8.	Antithrombotics	Xolair <sup>™</sup>	0	0.4%	0.4%
9.	Antihyperlipidemics	Crestor <sup>®</sup>	0.4%	0.1%	0.3%
10.	Misc. CNS Agents	Xyrem <sup>™</sup>	0.3%	0	0.3%
11.	Oral Contraceptives	N/A	0	0	0
12.	Antiasthmatics	N/A	0	0	0
13.	Antihypertensives	N/A	0	0	0
14.	Antidiabetics	N/A	0	0	0
15.	Decongestants	N/A	0	0	0
16.	Gastrointestinals	N/A	0	0	0
17.	Antidepressants	N/A	0	0	0
18.	Narcotic Analgesics	N/A	0	0	0
19.	Anticonvulsants	N/A	0	0	0
20.	Calcium Blockers	N/A	0	0	0
21.	Beta Blockers	N/A	0	0	0
22.	Quinolones	N/A	0	0	0
23.	Antipsychotics	N/A	0	0	0
24.	Macrolides	N/A	0	0	0
25.	Estrogens	N/A	0	0	0
Top 25			0.3%	0.8%	0.9%
Other			0.3%	0.2%	0.5%
Total			0.3%	0.4%	0.7%

#### UNITS PER PRESCRIPTION

The impact of units per prescription traditionally has been the least significant factor influencing overall trend. In 2003, this pattern did not change as units returned trend by 0.1%. More variability, however, was seen between the classes. Narcotic analgesics, with an increased units trend of 6.2%, and antineoplastics, with a units trend of -6.6%, demonstrate that this component can have a significant impact on individual class trend even though the overall impact is small.

The units trend is particularly interesting for narcotic analgesics. From 2.7% two years ago, it rose to 4.7% in 2002 and then to 6.2% in 2003. This pattern suggests that more members are taking narcotics on a maintenance basis rather than on an acute basis.

*Changes in Units per Prescription for the Top 25 Therapy Classes 2002 to 2003  
Ranked by Percent Change*

Rank	Therapy Class	% Change Units per Prescription
1.	Narcotic Analgesics	6.2%
2.	Dermatologicals	3.3%
3.	Stimulants/Anti-Obesity	2.3%
4.	Gastrointestinals	0.7%
5.	Beta Blockers	0.6%
6.	Antidiabetics	0.6%
7.	Microlids	0.6%
8.	Antihistamines	0.5%
9.	Antihypertensives	0.4%
10.	Antiparasitics	0.3%
11.	Quinolones	0.2%
12.	Misc. Endocrines	0.1%
13.	Antidepressants	0.1%
14.	Anti-Rheumatics (NSAIDs)	0
15.	Calcium Blockers	-0.1%
16.	Oral Contraceptives	-0.1%
17.	Antihyperlipidemics	-0.5%
18.	Antivirals	-0.6%
19.	Migraine Products	-0.6%
20.	Decongestants	-1.5%
21.	Antipsychotics	-1.6%
22.	Misc. CNS Agents	-1.8%
23.	Anticonvulsants	-1.9%
24.	Estrogens	-3.7%
25.	Antineoplastics	-6.6%
	Top 25	0.1%
	Other	-0.6%
	Total	-0.1%

Exhibit 14

Brand/generic mix reflects the cost impact of increased generic use. At -2.5%, the offset of trend by brand/generic mix matched its greatest impact in the three years that this component has been measured. As shown in Exhibit 14, negative brand/generic mix trends (i.e., increased use of generics) were seen in 19 of the 25 top classes for 2003. Only two classes experienced a positive brand/generic mix, while four of the top 25 classes showed no appreciable change. Contributing substantially to this trend was the 2003 introduction of generics for blockbuster brands, such as Ortho-Novum® 7/7/7 and Paxil®. Additionally, the generic equivalents for drugs such as Piroxicam® and the pain drug Ultram®, which both lost patent protection in 2002, continued to erode brand market share.

In 2003, the effects of generic substitution were felt in classes outside of the top 25 as well. For example, peritillins dropped from 24th to 30th place in the ranking by cost as a result of a 20.4% decrease in brand/generic mix. In the next few years, other classes of antibiotics, such as quinolones and macrolides, may also drop out of the top 25 in drug spend as generic competition becomes available for key products.

As discussed in the pharmacy benefit guide section, plan sponsors that implemented step therapy were able to benefit more fully from generic introductions in the gastrointestinal, antihypertensive, antidepressant and antidiabetic classes.

Brand/Generic Mix for the Top 25 Therapy Classes 2002 to 2003  
Ranked by Percent Change

Rank	Therapy Class	Key Patent Expirations in 2003	% Change Brand/Generic Mix
1.	Oral Contraceptives	Ortho-Novum® 7/7/7	-7.8%
2.	Gastrointestinals	Piroxicam®	-7.4%
3.	Narcotic Analgesics	Ultram®	-6.8%
4.	Antineoplastics	Midazolam®	-5.8%
5.	Antihypertensives	Prinivil® / Losartan®	-5.1%
6.	Dermatologicals	Accutane®	-4.5%
7.	Stimulants/Anti Obesity	Adipex®	-4.0%
8.	Antidepressants	Paxil® Serzone®	-2.1%
9.	Calcium Blockers	Adalat®CC, Iltazac®	-2.1%
10.	Antidiabetics	Glucophage®	-1.2%
11.	Anticancerals	Mysoline®	-0.9%
12.	Estrogens	Climara® Estrace®	-0.8%
13.	Beta Blockers	Kelone®, Metoprolol®	-0.6%
14.	Antihistamines	N/A	-0.4%
15.	Anti-Rheumatics (NSAIDs)	Relafen®	-0.3%
16.	Anticholinergics	Valmax®	-0.2%
17.	Decongestants	Atrovent®	-0.2%
18.	Antivirals	Flumadine®	-0.1%
19.	Antipsychotics	N/A	-0.1%
20.	Antihyperlipidemics	Nevator®	0
21.	Quinolones	N/A	0
22.	Migraine Products	N/A	0
23.	Misc. CNS Agents	N/A	0.1%
24.	Macrolides	N/A	0.3%
25.	Misc. Endocrines	N/A	-2.4%
	Top 25		-3.1%
	Other		-2.5%
	Total		-2.5%

34 express scripts

35

## THERAPEUTIC MIX

Changes in the cost per prescription, due to the use of more expensive or less expensive drugs and drug strengths, make up the component of therapeutic mix. The therapeutic mix change from 2002 to 2003 indicates a 3.2% growth in costs due to the use of more expensive drugs. Of the top 25 classes, seven experienced a decline in therapeutic mix while only two, antipsychotics and narcotic analgesics, rose by double digits. Mix changes among the antipsychotics were driven by increased use of the atypical antipsychotic medications, while increased use of sustained-release products, such as OxyContin<sup>®</sup> and Duragesic<sup>®</sup>, was responsible for much of the change in narcotic analgesics.

Particularly large decreases from last year were seen in the antihistamine and cough/cold product classes due to the launch of OTC Claritin. Claritin-D<sup>®</sup>, an antihistamine/decongestant combination product was included in the cough/cold class. Antihistamines were down by 7.6% from last year, and the cough/cold class dropped out of the top 25 with a -23.3% mix trend. Just as significant was the dramatic reversal in the antiviral class. Last year the antiviral class experienced a mix trend increase of 22.8%, but in 2003, its mix trend was actually a negative 7.1%.

*Price Changes Due to Therapeutic Mix for the Top 25 Therapy Classes 2002 to 2003  
Ranked by Percent Change*

Rank	Therapy Class	% Change Therapeutic Mix
1.	Antipsychotics	13.0%
2.	Narcotic Analgesics	11.0%
3.	Stimulants/Anti-Obesity	9.8%
4.	Anticonvulsants	8.7%
5.	Anti-Rheumatics (NSAIDs)	6.8%
6.	Misc. CNS Agents	6.7%
7.	Antisthmatics	6.1%
8.	Dermatologicals	3.8%
9.	Antidiabetics	3.3%
10.	Oral Contraceptives	3.3%
11.	Antihypertensives	2.8%
12.	Gastrointestinals	2.7%
13.	Antihypertensives	2.7%
14.	Beta Blockers	2.6%
15.	Decongestants	1.2%
16.	Antidepressants	1.1%
17.	Calcium Blockers	0.9%
18.	Macrolides	0.6%
19.	Antihyperlipidemics	-0.3%
20.	Quinolones	-0.9%
21.	Migraine Products	-1.3%
22.	Misc. Endocrines	-2.6%
23.	Estrogens	-4.3%
24.	Antivirals	-7.1%
25.	Antihistamines	-10.1%
	Top 25	3.6%
	Other	1.0%
	Total	3.2%



## INFLATION

The calculation of inflation is based on the AWP for each unit of a given product as reported on the day each prescription was filled. AWP was discounted by 12% for brands and 36% for generics. The inflation rate represents the difference between the weighted average discounted AWP per unit in 2003 for common drugs, while holding constant product market share, units per prescription and the brand/generic ratio. The inflation rate of 6.9% for 2003 was slightly lower than the 7.5% reported last year.

Therapy class inflation rates ranged from a high of 19.2% for estrogens to only 3% for antihistamines. Ironically, when ranked by drug cost rather than by number of prescriptions, estrogens were first last year with an inflation rate of 12.2%, and antihistamines were second at 11.8%. This disparity points out different strategies used by pharmaceutical manufacturers to cope with declining utilization. While manufacturers of estrogens apparently tried to preserve profits as their products fell out of favor, manufacturers of antihistamines kept prices in check, perhaps to remain competitive with OTC alternatives.

As seen in previous years, the 7.6% inflation rate for brands far exceeded the generic inflation rate of 3.3%, even though the brand rate was slightly lower than last year. Generic inflation increased only slightly from the 3.1% reported last year.

Price Changes Due to Inflation for the Top 25 Therapy Classes 2002 to 2003  
Ranked by Percent Change

Rank	Therapy Class	% Price Change		All
		Brand	Generic	
1.	Estrogens	20.2%	1.0%	19.2%
2.	Antineoplastics	13.6%	-5.4%	11.1%
3.	Diuretics	9.3%	1.3%	9.3%
4.	Quinolones	9.2%	N/A	9.2%
5.	Stimulants/Amphetamine-Related	10.3%	1.4%	9.0%
6.	Misc. CNS Agents	8.3%	18.7%	8.4%
7.	Dermatologicals	9.3%	6.2%	8.4%
8.	Oral Contraceptives	9.1%	3.7%	7.9%
9.	Anticancer	8.5%	1.5%	7.6%
10.	Anticancer	8.2%	1.1%	7.5%
11.	Anticancer	9.0%	-0.1%	7.4%
12.	Migraine Products	7.2%	0.5%	7.1%
13.	Beta Blockers	6.5%	7.0%	6.8%
14.	Antivirals	6.9%	-0.8%	6.5%
15.	Antipsychotics	6.7%	3.3%	6.5%
16.	Antihypertensives	8.0%	0.5%	6.3%
17.	Antidepressants	7.3%	1.1%	6.2%
18.	Antihypertensives	6.2%	2.9%	6.1%
19.	Narcotic Analgesics	8.7%	0.5%	5.8%
20.	Anti-Rheumatics (NSAIDs)	6.8%	0.9%	5.8%
21.	Macrolides	5.2%	6.0%	5.2%
22.	Misc. Endocrines	5.0%	0.4%	4.9%
23.	Gastrointestinals	4.4%	0	4.0%
24.	Calcium Blockers	4.1%	1.4%	3.2%
25.	Antihistamines	2.9%	23.7%	3.0%
	Top 25	7.3%	1.7%	6.5%
	Other	9.3%	6.4%	8.5%
	Total	7.6%	3.3%	6.9%

## UTILIZATION OF COMMON DRUGS

Despite decreases in common drug utilization among three classes — antihistamines, estrogens and migraine products — overall utilization of common drugs grew in 2003. At 6.8%, the increase was the greatest utilization growth in the last five years. Of the top 25 classes, 22 experienced increased utilization — 13 reached 10% or higher. Miscellaneous endocrine demonstrated the greatest growth in utilization due to continued consumer advertising as well as to patients switching from estrogens, which met with further safety concerns in 2003. The antihyperlipidemics continued to show significant growth in use due to more aggressive treatment guidelines.

The overall prevalence rate (the change in the proportion of members utilizing drugs) increased by 3%, accounting for about 44% of the overall utilization increase. Changes by therapy class largely mirrored the changes in utilization, with only seven classes showing declines.

Intensity, the change in the numbers of prescriptions filled among members utilizing drugs in a given class, increased by 3.7%, accounting for 55% of the overall utilization change. Only three classes — antihistamines, antitrials and estrogens — experienced a decline in intensity. While the estrogen decline was further evidence of the decreasing popularity of hormone replacement therapy, the declines in the other two classes may be due in part to increasing use of more combination products.<sup>12</sup> Miscellaneous CNS agents, antineoplastics and stimulants/anti-obesity — three classes with inconsistent changes in both prevalence and utilization — also were the only classes with intensity changes of 10% or more.

Utilization of Common Drugs for the Top 25 Therapy Classes 2002 to 2003  
Ranked by 2003 Percent Change

Rank	Therapy Class	PREVALENCE		INTENSITY		% Change	
		2002	2003	2002	2003	Prevalence	Intensity
1.	Misc. Endocrines	0.16	0.19	14.9%	6.0%	21.8%	6.0%
2.	Antihyperlipidemics	0.65	0.76	13.2%	3.6%	17.4%	3.6%
3.	Beta Blockers	0.42	0.48	11.1%	2.4%	13.8%	2.4%
4.	Anticonvulsants	0.17	0.20	12.1%	1.2%	13.5%	1.2%
5.	Antitrials	0.06	0.07	22.9%	-8.3%	12.7%	-8.3%
6.	Antihypertensives	0.86	0.96	10.7%	1.5%	12.4%	1.5%
7.	Misc. CNS Agents	0.03	0.03	-3.2%	16.0%	12.3%	16.0%
8.	Oral Contraceptives	0.40	0.45	6.1%	5.7%	12.1%	5.7%
9.	Gastrointestinals	0.50	0.56	6.8%	4.8%	12.0%	4.8%
10.	Antidiabetics	0.44	0.49	10.4%	1.2%	11.7%	1.2%
11.	Antidepressants	0.72	0.80	6.6%	4.2%	11.2%	4.2%
12.	Antineoplastics	0.05	0.05	-0.8%	10.7%	10.0%	10.7%
13.	Macrolides	0.18	0.20	8.8%	1.1%	10.0%	1.1%
14.	Antipsychotics	0.37	0.40	10.4%	-0.5%	9.9%	-0.5%
15.	Antispasmodics	0.06	0.06	3.5%	9.3%	9.0%	9.3%
16.	Narcotic Analgesics	0.46	0.50	4.5%	2.8%	7.4%	2.8%
17.	Decongestants	0.15	0.16	4.1%	2.4%	6.6%	2.4%
18.	Anti-rheumatics (NSAIDs)	0.40	0.43	1.0%	4.5%	5.6%	4.5%
19.	Stimulants/Anti-Obesity	0.00	0.09	-9.1%	13.4%	3.1%	13.4%
20.	Calcium Blockers	0.31	0.32	1.3%	0.4%	1.7%	0.4%
21.	Dermatologics	0.30	0.31	-0.1%	1.3%	1.3%	1.3%
22.	Quinolones	0.10	0.11	6.2%	0.3%	0.4%	0.3%
23.	Migraine Products	0.06	0.06	-2.7%	2.1%	-0.6%	2.1%
24.	Antihistamines	0.37	0.31	-17.3%	3.3%	-14.8%	3.3%
25.	Estrogens	0.43	0.31	-27.1%	3.4%	-29.6%	3.4%
	Top 25	7.77	8.33	2.9%	4.1%	7.2%	4.1%
	Other	3.54	3.76	3.2%	2.8%	6.1%	2.8%
	Total	11.31	12.09	3.0%	3.7%	6.8%	3.7%

<sup>12</sup> Ann A. Two for women? Combo pills may help patients — and are sure to help drug firms. *Washington Post* (January 17, 2004, p. H01). Available at: <http://www.washingtonpost.com/wp-dyn/content/article/2004/01/17/2004-01-17.html>. Accessed January 23, 2004.

Components of Unmanaged PMPY Cost Trend 1998 to 2003\*

	1998/1999	1999/2000	2000/2001	2001/2002	2002/2003	PMPY 2003 SPEND INFLATION
Inflation	5.4%	5.4%	5.6%	7.5%	6.8%	6.6%
• Units per Rx	0.2%	1.0%	0	-0.1%	0.1%	0.3%
• Brand/Generic Mix			-1.4%	2.3%	-2.5%	-2.6%
• Therapeutic Mix	3.1%	5.1%	4.4%	5.3%	3.2%	2.6%
• Utilization	5.2%	3.7%	6.3%	0.3%	6.8%	6.6%
• Common Drugs	15.6%	16.9%	16.6%	17.5%	14.8%	14.0%
• New Drugs	1.8%	0.3%	1.0%	1.0%	0.7%	0.5%
• All Drug	17.4%	16.2%	16.7%	18.5%	15.5%	14.5%

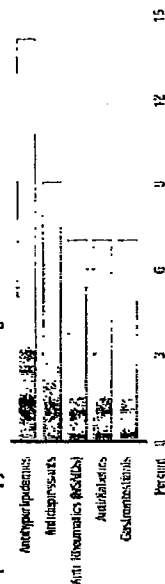
\* The percentage contribution of each factor does not add to the All Drug percentage increase. The inflation index (the best cost) for a given year and multiplied by one times the percentage contribution by the next factor (utilization). The resulting total is then multiplied by the percentage contribution by the next factor (brand/generic mix) and so on for each Common Drug Factor. The percentage contribution of the New Drugs is then added to the total Common Drug percentage to yield the All Drug percentage increase. The final results may differ due to rounding.

The prevalence of prescription drug use increased by 3 percentage points from 2002 to 2003, consistent with last year's increase. Of the 2.1 million members in the 2003 Drug Trend Report sample, 61.1% filled at least one prescription, up from 58% in 2002. Small changes were seen in the intensity of use, with its impact on trend increasing from 3.3% to 3.7%. In actual numbers, the average prescription drug utilization in the 2003 Drug Trend Report sample took 15.5 prescriptions in 2003, up from 15.1 in 2002.

Interesting but not surprising was that a small number of therapy classes accounted for most of the growth in drug spend. As shown in Exhibit 10, antihyperlipidemics alone accounted for nearly 14% of the growth in prescription drug spend. The second greatest contributor was antidepressants, which were responsible for nearly 10% of the 2003 drug trend. The top five therapy classes were responsible for nearly 45% of the growth in drug spend, and the top 10 classes accounted for more than two-thirds of the increased drug spend. This concentration was even greater than last year, when the top 10 classes accounted for 58% of growth in costs, due to the dramatic decline in spending for several classes.

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Top Five Therapy Classes Contributing to 2003 Trend



17 18 19 20 21 22 23 24 25 26 27

The 2002 to 2003 PMPY ingredient cost trend was analyzed in terms of the following three major dimensions:

- Changes in the utilization of common drugs (prescription medications that were dispensed in both 2002 and 2003)
- Changes in the ingredient cost per prescription of these common drugs
- Introduction of new products to the market (prescription drugs dispensed in 2003 but not in 2002)

Utilization of common drugs was further divided into two components: prevalence and intensity. Prevalence tracks the proportion of members who fill one or more prescriptions from one year to the next (i.e., users). Intensity is the number of prescriptions filled by users from one year to the next.

Per-prescription costs were separated into the relative effects of four factors:

- Inflation
- Units per prescription
- Brand/generic mix
- Therapeutic mix

The impact of new drugs was divided into two independent contributions. First is the change in per prescription cost (the differential between the cost of new drugs and the average cost of common drugs). The second new drug factor is the added costs associated with increased utilization of new drugs.

The remainder of this section presents general discussions for the 25 most costly therapy classes according to each of the trend components: utilization, inflation, therapeutic mix, units per prescription and new drugs. Detailed reviews for each therapy class are included in the following section.

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### *Overall Drug Trend*

In 2003, PMPY ingredient costs for unmanaged prescription drugs, including specialty drugs that were reimbursed as part of the pharmacy benefit, rose to \$676.50, a non-discounted (i.e., prior to network and formulary discounts) 15.5% increase over 2002. Just over 48% of the increase was due to higher cost per prescription, 47.2% was due to more utilization of drugs, and 4.5% was due to the use of drugs that were not available in 2002. Express Scripts clients now manage these costs extensively, experiencing lower trends of between -5% and 10%, depending on the extent of management.

Many of the new drugs introduced in recent years are specialty drugs — mainly products of biotechnology, developed to treat conditions that previously had few, if any, effective drug therapies. At the same time, the number of specialty drugs to treat specific conditions has expanded, often giving prescribers and patients new options for drug treatment. In addition to growing prevalence of use, specialty drugs are increasingly likely to be covered under the prescription drug benefit rather than the medical benefit. However, the substantial development costs, the relatively small populations that need these products, and the special handling required for their transport and administration makes prescriptions for these products considerably more expensive than most other types of drugs. Against this backdrop, we present trend for specialty drugs separately this year.

As shown in Exhibit 9, PMPY drug trend was 14.5% from 2002 to 2003, with specialty drugs excluded. This trend is 4 percentage points lower than the previous year, primarily due to less movement towards the use of more expensive brands. In contrast, trend for specialty drugs was 38.7%, which was lower on a percentage basis compared to 2001 versus 2002, but the same on a dollar basis. The vast majority of growth in specialty spend was due to greater utilization. A more detailed discussion of trends in specialty drugs follows the discussions of individual components, which make up unmanaged drug trend.



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*Notes*

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## INTRODUCTION

a standard discount of 12% for brand products and 36% for generic products off of the AWP cost per unit. The discount figures used are not meant to represent actual client discounts. Rather, they reflect the roughly three-to-one ratio between the magnitude of brand and generic discounts that apply to the Express Scripts book of business. Relative to using AWP as the cost basis, this discount differential more accurately captures the impact that dramatic increases in generic fill rates have had on pharmacy costs over the last few years. It should be noted that while all generics are discounted at the same rate in this Report, actual generic discount rates can vary significantly for specific products.

As in previous Reports, prescription counts have been converted to equivalent quantities that would have been dispensed through retail pharmacies to adjust for differential mail use rates and varying benefit structures across Express Scripts clients. Neither non-prescription drugs nor prescriptions dispensed in inpatient settings are included in this analysis. Finally, overall figures will not represent actual individual client experience due to differences in plan design.

The samples used in this study consist of 2.1 million unique members from 2002 and 2003. The member sample for 2002 is different from the sample analyzed for the 2002 *Drug Trend Report*. To prevent significant distortion in the sample, membership from any given client was limited to no more than 5% of the overall sample. The average age of the 2002 sample was 34, and the average age of the 2003 sample was 34.4.

To ascertain the variable use patterns across the spectrum of drugs used by members sampled for the 2003 *Drug Trend Report*, drugs were categorized into therapy classes, groups of pharmaceutical agents that are chemically or therapeutically related. Therapy classes were defined by the first two digits of the 14 digit Generic Product Identifier (GPI) code maintained by the Facts and Comparisons division of Wolters Kluwer Health, Inc.

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## REPORT CHANGES

This year's *Drug Trend Report* has been modified to allow for easier reference. In addition to the overall trend summary tables, trend components by therapy class and forecast, we have included a two-page review on each of the top 25 therapy classes that contribute to drug spend. These therapy class outlines present an overview of all the trend components for that class along with a discussion of the reason(s) for the observed change. In addition, market share charts, pipeline tables and patent expiration information, which were previously in separate sections of the Report, have been included in each therapy class summary. Following the discussion of drug trend, an expanded section on pharmacy benefit management is included to advise plan sponsors of the tools they can adopt to manage drug spend.

In previous years, therapy classes were ranked by the number of prescriptions dispensed. To better reflect overall trend, a different scale, PMPY spend, was used to rank the classes for this Report.

## METHODS

The analyses contained in the 2003 *Drug Trend Report* are based on prescription medication usage for a sample of Express Scripts commercial (i.e., not Medicare or Medicaid) clients that maintained individual member eligibility data in both 2002 and 2003. These clients used Express Scripts for both retail and mail pharmacy services. They also offered a funded benefit, meaning that the client providing the pharmacy benefit paid at least some portion of the cost for prescriptions dispensed to its members. Medicaid recipients and Medicare beneficiaries receiving drug coverage through Medicare Advantage (formerly Medicare+Choice) plans are excluded from this study because of their unique demographics and drug coverage policies. About three-fourths of the resulting 2003 sample consists of non-managed care commercial members, and about one-fourth is managed care commercial members.

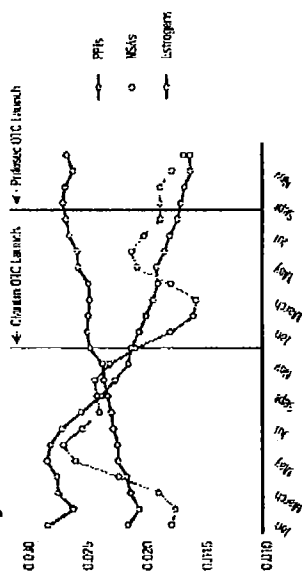
Cost data included in this report are expressed on a discounted Average Wholesale Price (AWP) ingredient cost basis. AWP is the retail list price of the medication as reported by First Databank. As in previous years, to ensure comparability across time periods and client groups, only discounts were included in cost calculations. Ingredient costs were computed using

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## INTRODUCTION

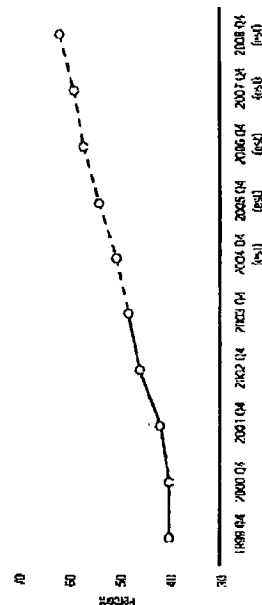
## INTRODUCTION

## PPI/PA Utilization of Non-Sedating Antihistamines, Proton Pump Inhibitors And Estrogens 2002 to 2003



The number of generic options grew in 2003 as generics for frequently-used brands, such as Augmentin<sup>®</sup> and Paxil<sup>®</sup>, also made dramatic impacts on the cost structure of their respective therapy classes (penicillins and antidepressants). Due to these generic launches and the growing use of stop therapy and other generic-promotion programs, the overall generic fill rate in the entire Express Scripts book of business reached an all time high in the fourth quarter of 2003 at 48% (Exhibit 7).

## Generic Fill Rate Fourth Quarter 1999 to Fourth Quarter 2008 (Estimated)

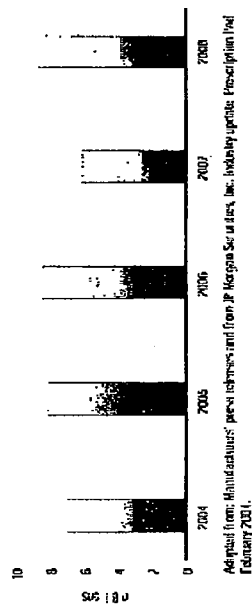


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## INTRODUCTION

Greater generic use is likely to continue. With many blockbuster drugs scheduled to lose patent protection in the next few years, products that account for over \$38 billion in sales are expected to have generic competition by the end of 2008 (Exhibit 8).

## U.S. Sales for Brand Products With Patent Expirations Between 2004 and 2008



## PROJECTIONS OF INGREDIENT COST TRENDS FOR UNMANAGED CLIENTS FROM 2004 THROUGH 2008

Based on past experience with and future expectations about the magnitude of unmanaged drug cost increases on an ingredient cost basis, per member per year (PMPY) ingredient costs are projected to increase by:

- 14.1% in 2004
- 14.8% in 2005
- 15.5% in 2006
- 15.3% in 2007
- 15.3% in 2008

By adopting proven trend management tools recommended in the pharmacy benefit guide section of this Report, plan sponsors can achieve single digit or even negative drug trend.

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## INTRODUCTION

## MARKET TRENDS IN PRESCRIPTION DRUG USE

Even without widespread use of aggressive benefit designs, several events combined to dampen prescription drug utilization increases in 2003. The introductions of new over-the-counter (OTC) versions of Claritin<sup>®</sup> and Pseudo<sup>®</sup> contributed to declines in the utilization of their respective therapy classes — non-sedating antihistamines (NSAs) and proton pump inhibitors (PPIs).

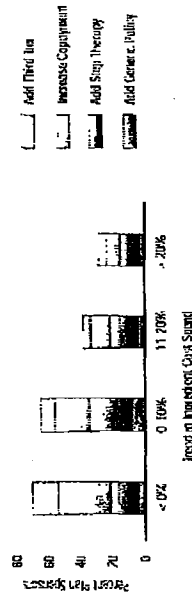
Exhibit 6 shows the month-by-month utilization of these therapy classes from March 2002 through December 2003. The utilization of NSAs showed a marked decline in the month following the introduction of OTC Claritin, which caused the complete withdrawal of all forms of lorazepam (the generic for Claritin) from the prescription market. In contrast, the PPI class showed little drop in use following the launch of Prilosec<sup>®</sup> OTC, likely due to the different clinical indications of OTC versus prescription versions as well as the availability of omeprazole (generic Prilosec) in prescription form.

The estrogen class also showed a substantial utilization decline in 2003 as risks associated with long-term use continued to be revealed.<sup>9, 10, 11</sup> As shown in Exhibit 6, the number of per member per month (PMPM) estrogen prescriptions declined from 0.28 in March 2002 to 0.17 in December 2003.

expensive medications, both brands and generics, and a slower growth in utilization. The lower trend from a copayment increase results from a slowing in utilization growth as the copayment increases. Express Scripts has done extensive research on the impact of increased copayments and has found no unintended consequences (e.g., more emergency room visits) from higher copayments. (See the pharmacy benefit guide section for details.)

Plan sponsors with 0-10% trend were more likely to have implemented step therapy (26% did so) for one or more therapy classes. Step therapy leads to savings for plans and members by promoting the use of much less expensive medications — typically generics. Obviously, the greater number of step therapy programs adopted, the greater the savings. Finally, a generic policy, which requires the member to pay the difference in price between a multi-source brand and its generic equivalent if the member chooses to get the brand, was more commonly adopted among plans with 0-10% trend in ingredient cost spend.

Pharmacy Benefit Management Activities by Drug Trend Achieved



<sup>9</sup> Gandy D, Harrington D, Ertter V, et al for the HERS Research Group. Cardiovascular disease outcomes during 6.8 years of hormone therapy: Heart and Estrogen/progestin Replacement Study Follow-up (HERS II). *Journal of the American Medical Association*. 2002;288(13):49-57.

<sup>10</sup> Hulley S, Luben J, Barrett-Connor E, et al for the HERS Research Group. Cardiovascular disease outcomes during 6.8 years of hormone therapy: Heart and Estrogen/progestin Replacement Study Follow-up (HERS II). *Journal of the American Medical Association*. 2002;288(13):58-64.

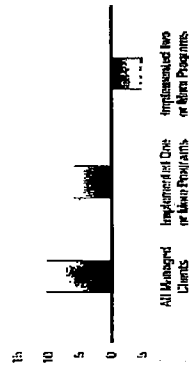
<sup>11</sup> Stumcken SH, Legault C, Krupp SR, et al for the WHIMS Investigators. Estrogen plus progestin and the incidence of dementia and mild cognitive impairment in postmenopausal women: the Women's Health Initiative Memory Study: a randomized controlled trial. *Journal of the American Medical Association*. 2003;289(20):2551-2607.

## INTRODUCTION

## TRENDS IN EXPENDITURES FOR PRESCRIPTION DRUGS

As a result of increased management of the pharmacy benefit, trends in ingredient cost and plan cost (i.e., net cost) spending diverged in 2003. Overall, trend in unmanaged ingredient cost spending was up 14.5%. However, nearly two thirds of Express Scripts clients had in place at least one management tool, such as three-tier copayments or step therapy programs. These plan sponsors experienced an average net cost trend of 10.4%. Furthermore, plan sponsors that implemented one or more tools for the first time in 2003, as recommended in the Express Scripts *Pharmacy Benefit Guide*, experienced a net cost trend of 5.9% from 2002 to 2003, depending on the specific tool(s) adopted. Plans that implemented two or more tools for the first time saw a net decrease of 4.6% (Exhibit 4). Many of the plans that implemented step therapy did so in mid-year, thus their savings will continue to build in 2004.

Net Drug Trend From 2002 to 2003



Despite the increased member responsibility among plans with low or negative trend, member responsibility remained under 25%, a percentage that is consistent with members' expectations when they are asked about what portion of drugs costs they should bear. Equally important, member satisfaction with Express Scripts remained steady in 2003 at 94.2%.

Exhibit 5 shows the types of management activities adopted by plan sponsors achieving different levels of trend. Plan sponsors with no change or a decrease in ingredient cost spending between 2002 and 2003 were more likely to have implemented a three tier copayment (16% did so) or increased the copayment for formulary brands (33%). Three-tier ingredient cost savings result from increased use of less

Similarly, the number of plan sponsors adopting closed formularies grew in 2003. A phased approach was popular, allowing plan sponsors to close a selected group of therapy classes over time rather than closing all therapy classes at once. This phased approach helped to balance cost-savings against member disruption. Also growing in popularity was Express Scripts High Performance Formulary, which consists primarily of generics and low-cost brands. The 10 plan sponsors that have adopted this formulary since 2002 have experienced significant reductions in total drug spend.

In addition to encouraging the use of lower cost medications, plan sponsor increasingly promoted lower-cost distribution channels for prescriptions. The national use of mail service grew by 8% in numbers of prescriptions filled and 15.5% in dollar amount during 2003.<sup>7</sup> Express Scripts experienced more than a twofold increase in the number of clients participating in mail awareness and education in 2003.

Recognizing that utilization growth is responsible for much of the increase in prescription drug spend, plan sponsors also tried several innovative strategies aimed at curbing utilization that is not cost-effective. Examples included four-tier copayments for lifestyle drugs, defined contribution plans and Internet based tools to educate members on prescription drugs.<sup>8</sup>

Express Scripts consumer oriented plan design, Express Choice<sup>SM</sup>, grew tenfold in member enrollment since 2002, with plan sponsors experiencing significant savings (range of 15% to 3% trend observed) while maintaining member satisfaction. Finally, a zero copayment option, currently employed by only a handful of clients, but gaining traction, allows a member taking a brand to switch to a therapeutically equivalent generic and pay no copayment for a limited time.

<sup>7</sup> IMS Health, National Prescription Drug Audit Plus 2003 and IMS National Sales Perspectives, February 2, 2004.  
<sup>8</sup> Express Scripts was a participant in managing drug costs. Health Industry News, November 5, 2003. Available at: <http://www.healthbusiness.com/news/press.cfm?contentid=45773>. Accessed February 24, 2004.

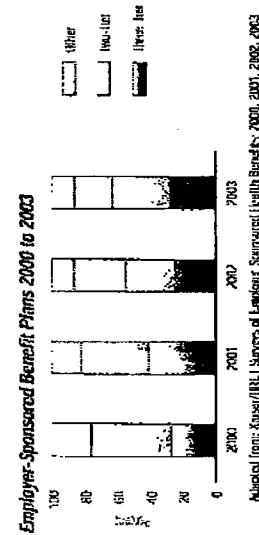
## INTRODUCTION

**PLANS TAKE THE MOST AGGRESSIVE ACTION SEEN IN THE PAST EIGHT YEARS**

In 2003, plan sponsors were much more active in managing drug costs than previously, adopting a variety of proven as well as innovative management tools. Plan sponsors increased member cost share to ensure that members were paying a fair share of the prescription drug spend. For example, Express Scripts clients increased copayments for formulary brands by more than \$5 between 2002 and 2003. Despite this increase, overall member cost sharing remained at less than 25% of total drug spend.

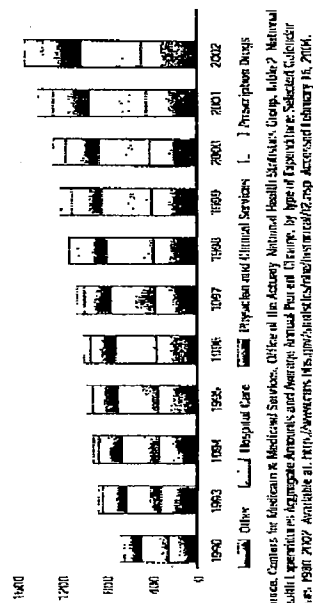
In addition to higher member cost-share, plan sponsors increasingly adopted tools to encourage the use of lower cost medications, both brands and generics. Among Express Scripts members, the use of step therapy grew from 4.5 million to 9.8 million lives, and the number of step therapy modules per life grew from 2.5 to 4.6 between the end of 2002 and the beginning of 2004. Each step-therapy program covering a drug class or subclass (i.e., SSRI antidepressants) is considered to be a separate module. This growth, which follows extensive Express Scripts research on the financial and clinical impact of step therapy, reflects recognition among plan sponsors that step therapy represents the most cost-effective way to promote generic use. In 2003, step therapy programs contributed more than a 2 percentage point increase in the generic fill rate for clients that implemented key step-therapy modules in January 2003.

Another popular strategy to promote the use of cost-effective medications in 2003 was the three-tier copayment, which assigns generics the lowest copayment, formulary brands the middle copayment and nonformulary brands the highest copayment amount. Nearly two-thirds of Express Scripts commercial clients had a three-tier copayment in 2003. Nationally, this percentage reached about 60% in 2003 (Exhibit 3).



On the public side, healthcare provision puts additional strain on already strapped state budgets. Even as more unemployed families become financially eligible for publicly financed benefits, states have had to make deep cuts in Medicaid and similar services. According to survey information released in January 2003 by the Kaiser Commission on Medicaid and the Uninsured, about half of the states are pursuing ways to curb their costs for prescription drugs under Medicaid. At the time of the survey, representatives of 12 state Medicaid agencies said that they would require prior authorization for more drugs; nine were beginning or extending lists of preferred products; eight were seeking higher discounts for their prescription drug purchases; seven were establishing or raising participant copayments; five were asking pharmaceutical manufacturers for supplemental rebates; and two were requiring generics. Nine states were planning to use additional strategies, such as limited days' supplies, step therapy and stricter maximum allowable cost (MAC) lists. Five states were also re-imposing limits on the number of prescriptions that can be filled per given time period.<sup>14</sup>

Against this backdrop and with the continued growth in spending for prescription drugs (Exhibit 2), it is hardly surprising that many dramatic changes in the management of the pharmacy benefit occurred in 2003.

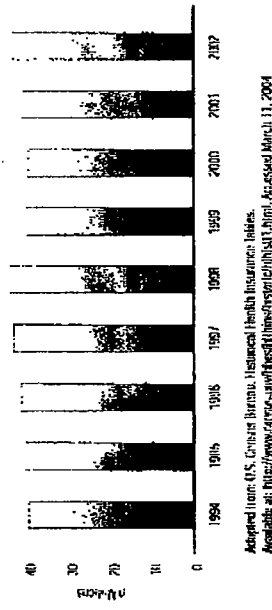
**National Health Expenditures for Selected Healthcare Accounts 1990 and 1993 to 2002**

<sup>14</sup> Stuart V. Little, I. Griffee, K. Ramakrishna, and W. W. Winkler, "Medicaid Spending Growth: A 50-State Update for Fiscal Year 2003," Kaiser Commission on Medicaid and the Uninsured, January 2003. Available at: <http://www.kaisercommission.org/pubs/030114.pdf>. Accessed March 11, 2004.

## INTRODUCTION

limited access to healthcare.<sup>5</sup> Individuals with no health insurance may put off routine medical care, potentially entering the health care system with relatively serious health problems that might have been controlled through regular checkups.

U.S. Uninsured Rate 1994 to 2002



The economic slowdown affects retirees, as well. Employer-sponsored health benefits are a major source of medical care that might be economically impossible for many retirees to obtain with Medicare alone. The majority of firms offering retiree benefits also cover other retiree family members – usually spouses and often dependents. In the early 1990s, however, many companies placed limits on the amount of retiree benefits they would contribute. Once the limit is reached, retirees are expected to meet more of the total obligation – typically as higher premiums, copayments and deductibles. Some employees are limiting coverage to the retiree only, and in other companies, future retirement benefits for individuals who are still working have been reduced or eliminated.

<sup>5</sup> U.S. Census Bureau, "Numbers of Americans with and without health insurance: Use, Census Bureau reports," (press release), September 30, 2003. Available at: <http://www.census.gov/Press-Release/www/2003/cbr03-154.html>. Accessed March 11, 2004.

benefits under the new Medicare prescription drug plan.<sup>6</sup> A Lewitt survey conducted in 2000 showed that prescription drugs accounted for about 50% of the costs to employer-sponsored retiree benefits for individuals 65 years old and older.<sup>7</sup>

In the interim, pharmacy benefit managers and other providers will be vying to offer a Medicare-endorsed prescription drug discount card, scheduled to begin on June 1, 2004. This temporary coverage is expected to offer a discount of about 25%, on average, off total prescription costs for beneficiaries without drug coverage and with incomes above 135% of the federal poverty level (FPL). Beneficiaries with incomes at or below 135% of the FPL will also receive a \$600 annual subsidy. Beneficiaries whose prescription costs exceed the subsidy will then pay the discounted cost of their medications.

In 2003, dramatic changes in healthcare coverage were not limited to the Medicare benefit. In tandem with significant increases in healthcare costs, the sluggish economy forced some big changes in the ways that companies provide healthcare benefits. The Kaiser Family Foundation reports that active employees were asked to contribute more in both premiums and copayments. Many employers explored alternative methods, such as healthcare spending accounts, to supplement traditional forms of insurance.<sup>8</sup> Not surprisingly, small companies, those with 20 or fewer employees, felt the cost increases most sharply. However, even very large employers reported seeking plan changes that helped to alleviate healthcare costs in 2003.

Greater unemployment has also led to loss of healthcare coverage in recent years. In 2002, an estimated 2.4 million additional people lost health insurance, adding to the total of 43.6 million U.S. citizens with

<sup>6</sup> Congressional Budget Office, H.R. 1, "Medicare Prescription Drug and Modernization Act of 2003," June 26, 2003 and S. 1, "Prescription Drug and Medicare Improvement Act of 2003," Congressional Budget Office Cost Estimate, June 18, 2003.

<sup>7</sup> McArdle, C., Gosselin, S., Gosselin, C., Friedman, D., Zelnick, A., "Implications of Medicare Prescription Drug Proposals for Employers and Retirees," Hewitt Associates for the Henry J. Kaiser Family Foundation, July 2003. Available at: <http://www.kff.org/medicare/loader.cfm?url=/mainpage/popup.asp&PageID=13590>. Accessed March 11, 2004.

<sup>8</sup> The Kaiser Family Foundation and Health Research and Educational Trust, "Employer Health Benefits, 2003 annual survey," Available at: <http://www.kff.org/insurance/03ba/abstract.cfm>. Accessed March 11, 2004.

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## Introduction

The future likely will show that 2003 was a watershed year, marked by many events destined to shape the pharmacy landscape for years to come. Significant developments in the healthcare market in 2003 included the poor economy, the loss of employer-sponsored prescription drug coverage by increasing numbers of the unemployed, growing state budget deficits, the new Medicare prescription drug benefit and the launch of over-the-counter (OTC) versions of some very popular prescription medications.

These events led plan sponsors to initiate a wide range of trend-management tools. As a result, plan sponsors clearly demonstrated in 2003 that managing the cost of prescription drugs is not beyond their control. Rather, drug trend is largely dependent upon the extent to which a plan sponsor actively manages the benefit to promote appropriate utilization and the use of less expensive medications when clinically appropriate. This Report explains the reason for the growth in drug spend, focusing on the key components of utilization, drug mix and new drug introductions. It also discusses pharmacy benefit management tools that plan sponsors can use to manage prescription drug spend.

## BACKGROUND

The most significant piece of healthcare legislation in 2003 and the most important legislation affecting pharmacy in decades was the passage of the Medicare Prescription Drug Improvement and Modernization Act of 2003, the largest expansion of Medicare since it was created in 1965. The benefit, which begins in 2006, will provide long-awaited relief to the millions of Medicare beneficiaries with little or no drug coverage. Medicare beneficiaries are not the only ones expecting relief from the cost of prescription medications. Over time, the legislation is also estimated to save a small group of large companies more than \$2.5 billion in the form of government subsidies designed to encourage employers to continue providing retiree health coverage.<sup>1</sup>

Despite the anticipated subsidies, the Congressional Budget Office estimated that approximately one-third of retired persons with health benefits through their former employers could lose all or part of those

<sup>1</sup> Francis T. Medicare drug law helps business *The Wall Street Journal* March 2, 2004.

# *INTRODUCTION*

# 1

2003

EXPRESS SCRIPTS DRUG TREND REPORT

## EXECUTIVE SUMMARY

The most significant step a plan sponsor can take to promote the use of generics is to implement Express Scripts High Performance Formulary (HPF), a formulary consisting primarily of generics and lower-cost brands. Branded products covered on the HPF are either in therapy classes without a clinically-equivalent generic or they are needed for clinical reasons. The HPF can provide a plan sponsor with immediate savings of as much as a 40% reduction in its current drug spend. Ten Express Scripts clients have experienced significant spending decreases after implementing the HPF. Given the growing number of generic medications, this formulary is likely to lead the market in new adoption in the near future.

Finally, Express Scripts consumer-oriented plan design, Express Choice, provides an alternative to defined-contribution plans. With Express Choice, plan sponsors offer multiple pharmacy plans that let members select the one that best meets their needs. Then, throughout the year, members experience the effects of their own decisions regarding cost, coverage and flexibility. By encouraging efficient use of the pharmacy benefit through Express Choice, plan sponsors consistently have seen significant reductions in trend while still maintaining member satisfaction.

In summary, plan sponsors demonstrated in 2003 that active management of the pharmacy benefit could lower drug trend dramatically. As we look to 2004 and 2005, plan sponsors have a variety of clinically appropriate trend-management tools at their disposal to promote the use of generics and lower-cost brands, thereby maximizing the value of the pharmacy benefit to their members.



## EXECUTIVE SUMMARY

## BENEFIT DESIGN

To avoid the forecasted double-digit trend in 2004, plan sponsors should implement programs that optimize use of the growing numbers of generic medications for key therapy classes. Five key programs for promoting use of cost-effective medications, both brands and generics, include the following:

- Tiered copayments
- Generic policy
- Step therapy
- High Performance Formulary
- Express Choice

Three-tiered copayments have become an industry standard because they align interests between the member and plan sponsor, provide financial incentive for the member to use the most cost effective alternative and still allow members a choice of medication. Express Scripts has done extensive research on three-tier copayments, finding that they can provide significant cost savings without any negative effects on clinical outcomes, such as medication compliance or other medical costs. Nearly two thirds of Express Scripts clients currently have a three-tier copayment design.

For brand medications with a generic equivalent (i.e., multi-source brands), a generic policy requires the member to pay the copayment plus the difference in price between the brand and generic medication if the member chooses to get the brand. Research has shown that the majority of members believe generics are just as good as brand medications. Accordingly, it is not surprising that plans implementing a generic policy experience no decrease in reported member satisfaction. About two-thirds of Express Scripts clients had a generic policy in 2003.

Step therapy programs are excellent tools for increasing use of generic medications because they extend a generic policy to promote therapeutic substitution. In a step therapy program, the use of a first-line medication, typically a generic, is required before coverage is provided for a second-line, typically more expensive brand medication. The number of therapy classes for which step therapy is appropriate has grown significantly in the past two years. Currently, more than 10 therapy classes are candidates for step therapy, and all of the top five therapy classes have step-therapy programs available.

Express Scripts has conducted extensive research on step therapy, finding significant savings and manageable member disruption. When implemented for just three therapy subclasses — proton pump inhibitors (PPIs), selective serotonin reuptake inhibitors (SSRIs) and non-steroidal anti-inflammatory drugs (NSAIDs) — step therapy produced a savings of \$140 per member affected, \$700 per call to the PBM, and \$4,600 for each call to the employer's human resources office.

*Step-Therapy Savings Offset Member Disruption*

Disruption	Savings
0.05% of members become disrupted	\$2,700/10 affected member
0.05% call HR	\$4,600/call
0.2% calls	\$700/call
1.0% affected	\$140/employee affected



## EXECUTIVE SUMMARY

In 2003, overall trend growth in ingredient cost, or unmanaged trend, reached 15.5%, which was not only the lowest rate of increase since 1997, but was also significantly less than the 18.5% seen in 2002. When specialty drugs are excluded, trend growth slowed even further to 14.5%. Spending on specialty drugs grew nearly 40% in 2003. The average cost per prescription for a specialty drug was \$1,223, up 2.5% from 2002, while utilization growth was up approximately 35%. The increase in specialty drug spend was driven primarily by the transfer of specialty-prescription management from the medical to the pharmacy benefit.

Utilization growth for common drugs (those approved in 2002 and earlier) reached an all-time high in 2003, contributing 47.2% to the overall trend increase. As in previous years, classes such as antihyperlipidemics and miscellaneous endocrine drugs led the utilization increase. However, some of the utilization growth came at a reduced overall cost. Four of the top 10 classes in utilization growth were also in the top 10 for brand/generic mix, which reflects the cost savings impact of increased generic use.

The percentage of prescriptions filled with generic drugs continued to grow, reaching 48% by the end of 2003. The increased use of step-therapy programs that promote generics as first-line products and the release of several high-profile generics each contributed to the increase. Currently, the pharmaceutical industry is in the largest patent expiration cycle it has ever seen, with products that account for \$38 billion in sales expected to have generic competition by the end of 2008.

## THERAPY CLASS HIGHLIGHTS

Antihyperlipidemics replaced gastrointestinal as the leading therapy class of 2003. Growing 23.8% from 2002, the annual per-member spend of \$64.11 for antihyperlipidemics represented almost 14% of the total growth in prescription drug spend. The top five categories (antihyperlipidemics, gastrointestinal, antidepressants, antihypertensives and anti-rheumatics) contributed nearly 45% of the growth in drug spend.

The impact from over-the-counter versions of Claritin<sup>®</sup> and Prilosec<sup>®</sup> that were launched in December 2002 and September 2003, respectively, was felt in the relevant therapy classes—antihistamines and gastrointestinal. Overall trend growth for the antihistamines was -20.9%, with both cost per prescription and utilization trends decreasing from 2002 levels. At 11.5%, growth in the gastrointestinal class was still substantial but significantly less than the 25% trend increase observed in 2002. In addition to the effects of Prilosec OTC<sup>®</sup>, generic competition for the prescription version of omeprazole (the generic for Prilosec) affected overall growth.

The estrogens class continued to be affected by the negative results of the Women's Health Initiative study, which prompted subsequent labeling changes that essentially limit the products to short-term use. Overall estrogen spend decreased by 23.2%, and utilization was down almost 30%.

As in previous years, drugs that were new to the market in 2003 contributed only modestly to overall drug trend growth. Only 10 of the top 25 therapy classes had a measurable change in trend due to new drugs. Strattera<sup>®</sup>, a new drug for attention deficit/hyperactivity disorder, had the greatest impact on drug spend, leading to more than a 40% growth in spend for its therapy class, stimulants/anti-obesity.

## FORECAST

Most drug pipelines, increased generic drug utilization and more aggressive trend-management programs will result in moderate drug trend growth through 2008. For unmanaged clients, Express Scripts forecasts an ingredient-cost trend growth rate of 14.1% for 2004. Continued increases in utilization should be offset by decreasing costs per prescription due to growing numbers of generic alternatives. The antihyperlipidemic therapy class will continue to lead in terms of overall spend, and the top seven therapy classes should remain constant for the next several years. With the strongest pipeline of new products, the antineoplastics class will be one to watch.

## EXECUTIVE SUMMARY

## Executive Summary

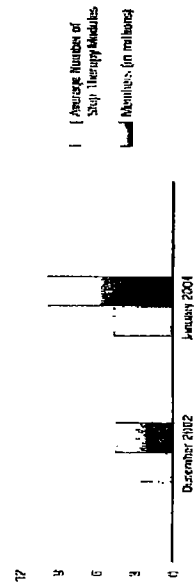
## MARKET TRENDS

As employers, health plans and other plan sponsors strive to provide affordable drug benefits to their employees and members, Express Scripts takes an evidence-based approach in developing customized programs and services that help plan sponsors reach their goals. By examining the latest trends in prescription drug utilization and spending, the *2003 Drug Trend Report* presents Express Scripts best thinking about the pharmacy benefit along with the latest research evidence that supports our consultative recommendations.

The year 2003 is likely to be seen as a turning point in healthcare due to several significant developments, including the new Medicare prescription drug benefit, the loss of employer sponsored prescription drug coverage, and the launch of over-the-counter (OTC) versions of several leading prescription products. As a result of such events, plan sponsors adopted a variety of proven and innovative management tools that made plan sponsors even more active in managing drug costs than in previous years.

Leading the way in new implementations were step-therapy programs designed to encourage the use of lower-cost medications, particularly generics. Among Express Scripts members, the use of step therapy grew from 4.5 million to 9.8 million lives from the end of 2002 to the beginning of 2004, as shown in the following exhibit. In addition, the number of step-therapy modules per life grew from 2.5 to 4.6 over the same time period. Each drug subclass for which there is a step-therapy program (e.g., SSRI antidepressants), is considered a separate module.

Members Enrolled in Plans With Step Therapy



4 express scripts

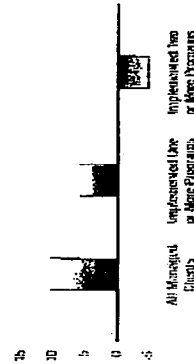
An ongoing strategy to promote the use of cost-effective medications in 2003 was the three-tier copayment, which assigns generics the lowest copayment, formulary brands the middle copayment and nonformulary brands the highest copayment amount. Nearly two-thirds of Express Scripts commercial clients had a three-tier copayment design in 2003. Also growing in popularity was Express Scripts High Performance Formulary, which consists primarily of generics and low-cost brands. The 10 plan sponsors that have adopted this formulary since 2002 are all experiencing negative trends in drug spend.

Reflecting the growing interest in consumerism, Express Scripts consumer-driven plan design, Express Choice<sup>SM</sup>, grew tenfold in member enrollment since 2002, with plan sponsors experiencing significant savings (range of -15% to 3% trend observed) while maintaining member satisfaction.

## DRUG TREND

Managed trend or drug-trend growth not of copayment for those plan sponsors who had at least one trend-management program by 2003 was 10.4%. As shown in the following exhibit, plan sponsors that implemented one or more tools for the first time in 2003, as recommended in the Express Scripts *Pharmacy Benefit Guide*, experienced a net cost trend of 5.9%, and those who implemented two or more tools for the first time in 2003 averaged a net cost trend of -4.6%. (Rebates, which were not considered, would have added to the trend reduction.) Despite increased member responsibility among some plans with low or negative trend, member responsibility remained under 25%, and member satisfaction remained steady at greater than 94%.

Net Drug Trend From 2002 to 2003



5

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2 express scripts

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## Preface

Dear Reader,

Last year, 2003, was a watershed year for pharmacy benefit management. It was filled with events that are likely to influence prescription drug utilization for years to come.

At the forefront was the enactment of the federal Medicare Prescription Drug Act. When fully implemented in 2006, this law will provide funded pharmacy benefits for American seniors — covering up to 50% of prescription drug costs for participating Medicare beneficiaries. It will also help to subsidize the costs of retiree prescription drug programs for corporations.

The debate over the Medicare bill put pharmacy benefit managers (PBMs) like Express Scripts in the spotlight, at times raising questions about PBM policies. In this context, Express Scripts issued its Client Pledge and decided to eliminate all non-rebate related funding from pharmaceutical manufacturers. By removing even the appearance of conflicting interests, Express Scripts led the way in creating a business model which clearly aligns our interests with those of our clients.

Last year also saw dramatic developments in pharmaceuticals.

- Claritin<sup>®</sup> went over-the-counter from prescription status;
- New study findings that uncovered additional adverse effects associated with taking estrogens caused an even bigger drop in estrogen usage;
- Several major prescription drugs, such as Prilosec<sup>®</sup> and Ortho Novum<sup>®</sup> 7/7/7 went generic. Among Express Scripts clients, the generic fill rate increased by 5% from 43% to 48%; and
- New studies showed the value of statins in conditions other than heart disease.

These developments resulted in lower use of some drugs (e.g., estrogens) and higher use of others (e.g., statins); but overall trend was lower because increased generic utilization held down general price increases.

Finally, the poor economy encouraged clients to adopt stronger cost-control measures to keep their cost trends at much lower rates than in the past — with aggressive management techniques, some Express Scripts clients actually saw cost decreases in 2003.

Sincerely,

*Barrett Toan*

Barrett Toan  
Chairman and Chief Executive Officer

PREFACE

### ***THE BOTTOM LINE***

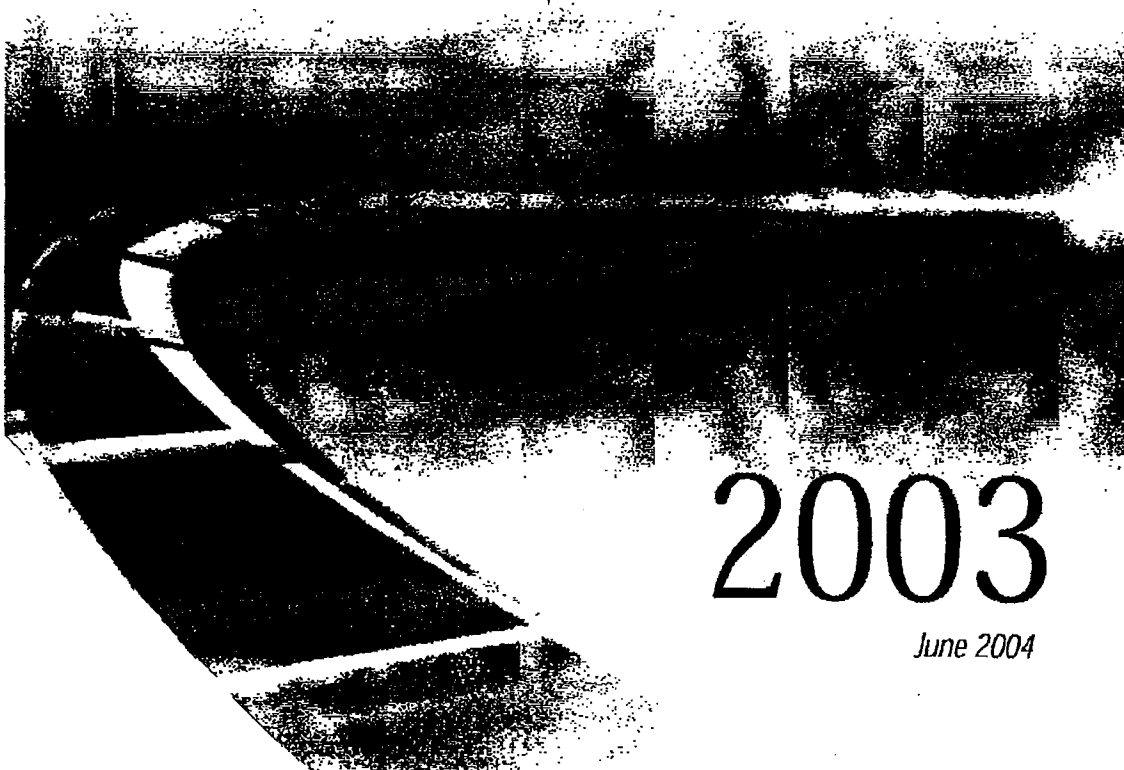
Per member per year (PMPY) ingredient costs continued to rise, increasing by 14.5% in 2003 for non-specialty drugs and 38.7% for specialty drugs. It is projected that without active management of the pharmacy benefit, PMPY drug costs will increase by 125% over the next five years.



EXPRESS SCRIPTS®

# ***DRUG TREND REPORT***

■ *Featuring The Pharmacy Benefit Guide*



# 2003

*June 2004*

# **Exhibit 7A**

Patricia Kay Morgan  
Volume II

HIGHLY CONFIDENTIAL - ATTORNEYS' EYES ONLY  
New York, NY

January 12, 2005

Page 319

1 HIGHLY CONFIDENTIAL - ATTORNEYS' EYES ONLY  
2 IN THE UNITED STATES DISTRICT COURT  
3 FOR THE DISTRICT OF MASSACHUSETTS

4 -----X  
5 In Re: PHARMACEUTICAL )  
6 )  
7 INDUSTRY AVERAGE WHOLESALE ) MDL No. 1456  
8 )  
9 PRICE LITIGATION ) CIVIL ACTION NO.  
10 ) 01-CV-12257-PBS  
11 )  
12 -----) Vol. 2  
13 THIS DOCUMENT RELATES TO )  
14 ALL ACTIONS )  
15 -----X

16 IN THE SUPERIOR COURT FOR THE STATE OF ARIZONA  
17 IN AND FOR THE COUNTY OF MARICOPA  
18 -----  
19 ROBERT J. SWANSTON, Individually and )  
20 on behalf of himself and all others )  
21 Similarly situated, )  
22 )  
23 Plaintiff, ) Case No.  
24 v. ) CV2002-004988  
25 )  
26 TAP PHARMACEUTICAL PRODUCTS, )  
27 INC., et al., )  
28 )  
29 Defendants. )  
30 -----

31 CONTINUED VIDEOTAPED DEPOSITION OF  
32 PATRICIA KAY MORGAN  
33 New York, New York  
34 Wednesday, January 12, 2005



Patricia Kay Morgan  
Volume II

HIGHLY CONFIDENTIAL - ATTORNEYS' EYES ONLY  
New York, NY

January 12, 2005

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Q. Does McKessen know that it is the  
only wholesaler that you are surveying for  
purposes of the markup?

MR. KERN: Lacks foundation.

A. No, I have not told them that.

Patricia Kay Morgan  
Volume II

HIGHLY CONFIDENTIAL - ATTORNEYS' EYES ONLY  
New York, NY

January 12, 2005

Page 586

1 C E R T I F I C A T E

2 STATE OF NEW YORK )

3 ) SS.:

4 COUNTY OF SUFFOLK )

5 I, FRANK J. BAS, a Registered  
6 Professional Reporter and Notary Public  
7 within and for the State of New York, do  
8 hereby certify:

9 That I reported the proceedings in  
10 the within-entitled matter, and that the  
11 within transcript is a true record of such  
12 proceedings.

13 I further certify that I am not  
14 related by blood or marriage, to any of the  
15 parties in this matter and that I am in no  
16 way interested in the outcome of this  
17 matter.

18 IN WITNESS WHEREOF, I have hereunto  
19 set my hand this 14th day of January, 2005.

20

21 FRANK J. BAS, RPR

22

# **Exhibit 8A**

RAYMOND S. HARTMAN  
UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS

 ORIGINAL

-----X  
NEW ENGLAND CARPENTERS HEALTH  
BENEFITS FUND, ET AL.,  
Plaintiffs

Civil Action

vs. No. 1:05-CV-11148-PBS

FIRST DATABANK, INC., and  
McKESSON CORPORATION,  
Defendants

-----X  
DEPOSITION OF RAYMOND S. HARTMAN, a  
witness called by and on behalf of the  
Defendant McKesson Corporation, taken pursuant  
Federal Rules of Civil Procedure, before  
Nicole E. Guilbert, a Notary Public in and for  
the Commonwealth of Massachusetts, at Bonner,  
Kiernan, Trebach & Crociata, on Wednesday,  
October 4, 2006, commencing at 9:46 a.m.

VOLUME I

1 RAYMOND S. HARTMAN

2 about whether some or all retailers knew about this change  
3 in 5 percent spread; am I correct?

4 A. I -- certainly, some -- I assume some did. I have  
5 not done a study whether all did.

6 Q. You don't need to know if a few or some or many  
7 were aware of the 5 percent change; am I correct?

8 A. That's right.

9 Q. You don't need to know that?

10 A. That's right.

11 Q. That's okay. Just tell me.

12 A. No. I said that's correct.

13 Q. Now let's go to PBMs. Did I understand you to say  
14 you assume PBMs did not know about the change in the 5  
15 percent?

16 A. What I'm saying is anybody who would look closely  
17 at the AWP and WAC and would analyze that on a day-to-day  
18 basis, which it is not -- given the nature of this  
19 industry, is not something that every participant does  
20 daily and is focussing on daily. There are certain inertia  
21 about what people observe and what they think is happening.  
22 But the PBMs could observe this on a day-to-day basis.  
23 Anybody could observe it on a day-to-day basis if they  
24 chose to.

25 Q. But what assumption do you make?

1 RAYMOND S. HARTMAN

2 based on the spread -- on the spread that was not  
3 understood by them.

4 Q. So I now have the foundation for the questions I  
5 want to ask. Tell me economically why is it if the  
6 third-party payors had been aware of ASP, what the ASP was  
7 and, therefore, the spread between the ASP and these  
8 artificially high AWP's, that would have not continued; that  
9 spread would not have -- have existed or continued in the  
10 marketplace? What is the economic principle behind that?

11 A. That that spread would --

12 MR. SOBOL: I'm sorry. I'm sorry.

13 Objection.

14 Q. (By Mr. Goldman) Yeah. The spread between the  
15 ASP and the -- these inflated AWP's, if it had been known to  
16 the third-party payors, what would they have done?

17 A. Well, I think Dr. Berndt -- I mean let's focus on  
18 those drugs that -- for which greater attention was -- was  
19 focussed on this issue and what Dr. Berndt has said in  
20 various places in his report is that there was -- when the  
21 spreads were unknown, when it was not clear what was going  
22 on, that there were possibilities for, I think he said,  
23 mischief and abuse; and that third-party payors, when they  
24 were made aware -- and these were large third-party payors  
25 -- were made aware of the size of this spread, they were

1 RAYMOND S. HARTMAN

2 flabbergasted. They were reimbursing off of an AWP that  
3 was so far above the acquisition costs of the doctor -- of  
4 the physicians, they were flabbergasted.

5 Judge Saris referred to these as "the mega  
6 spreads." Now, if I'm a third-party payor and doctors are  
7 coming to me and saying, well, look, I want to be  
8 reimbursed at AWP less 15 and I know that the doctors are  
9 getting this at what is 75 percent below that, so that  
10 would be a spread of three or four hundred percent on the  
11 ASP, they would have said, I'm not -- you know, I'm not  
12 going to pay you AWP less 15. I'm going to negotiate more  
13 aggressively.

14 Q. And that would have been what would have likely  
15 happened if the third-party payors were aware of what ASP  
16 actually was, correct?

17 A. If the third-party payors -- again, we have to --  
18 you know, we keep talking a little bit about this is  
19 hypothetical in Chicago school, you know, if they knew  
20 about this bid of excess fees, you know, there's going to  
21 be heat-seeking missiles that go and compete them away. I  
22 think we have to also keep in mind what Dr. Berndt put very  
23 well of the importance of being unimportant; that the drug  
24 spending generally has been one of the smallest elements of  
25 third-party payor reimbursement. So they haven't had swat

1 RAYMOND S. HARTMAN

2 teams focussing on those kinds of fees in trying to manage  
3 them closely. It's been on hospitals, physicians, other  
4 kinds of things.

5 But suppose we're in a state of the world where  
6 all that other stuff has been worked out by the third-party  
7 payors and they started to know about this information,  
8 which does not seem to be the case, as Dr. Berndt suggests  
9 over the period of the nineties, over much of the MDL  
10 period. They would use that information to try and  
11 negotiate aggressively if they -- if they had known about  
12 that.

13 Q. Okay. "If they had known about that" meaning  
14 about what ASP actually was?

15 A. That's correct.

16 Q. So they were missing one of the pieces to know  
17 what the spread was; they were missing what the ASP was,  
18 correct? They knew what the AWP was. They didn't know  
19 what the ASP was, correct?

20 A. That's correct.

21 Q. And I want to see if you'll agree with me, in our  
22 case, unlike what you found there, the spread that we're  
23 talking about here, as you point out in the footnote, AWP  
24 and WAC, the market -- people in the marketplace can learn  
25 both pieces of the equation to know the spread?



1 RAYMOND S. HARTMAN

2 assume that I have -- well, I have seen no evidence that --  
3 issues about expiration or negotiations off AWP that there  
4 was any evidence that reflected an understanding of this --  
5 of the allegations in this matter or -- or determined that  
6 behavior or those decisions at all. And so I wasn't -- I  
7 didn't -- I didn't focus on that.

8 Q. Sure. But based upon your experience in the  
9 industry and your knowledge about these contracts, would  
10 you expect to see contracts expiring every year during the  
11 class period?

12 A. Contracts expire and they -- they would expire --  
13 I don't know whether it's every year or I've --

14 Q. Well, you've seen one-year contracts; you've seen  
15 two-year contracts?

16 A. I've seen -- that's right.

17 Q. They would expire during the class period?

18 A. They would.

19 Q. Am I right? So based upon what you saw, you know  
20 some of the contracts are going to expire during the class  
21 period?

22 A. Some contracts would have expired during the class  
23 period.

24 Q. But you have no idea how many would be expiring  
25 every year during the class period, am I right, because you

1 RAYMOND S. HARTMAN

2 saying, look, we're -- we're talking to McKesson and we  
3 don't want this to be known and we want this to --

4 Q. Not part of my hypothetical. I want --

5 A. Your hypothetical is everybody knows -- the PBMs  
6 are fully informed their --

7 Q. I'm going to tell you my hypothetical again. The  
8 PBMs have become aware that the retailers are getting  
9 larger profits because of the 5 percent spread. Now, my  
10 question is: Will that lead to the PBMs imposing larger  
11 discounts upon their retail members?

12 A. There's not enough substance to your hypothetical  
13 to --

14 Q. What else would you need to know to answer my  
15 question?

16 A. How they became aware, the extent to which they  
17 became aware, how they would have negotiated. It's -- it's  
18 something that is certainly not part of anything that's in  
19 my declaration or the assumptions of my declarations or the  
20 allegations assumed here, and it certainly requires more  
21 substantive detail than what you've provided.

22 Q. Based upon your knowledge of the industry and your  
23 background in -- your large background in economics, if the  
24 PBM was aware that the retailers had this increased profit,  
25 wouldn't they -- wouldn't that likely lead to the PBM

1 RAYMOND S. HARTMAN

2 attempting to increase the discount off of AWP with their  
3 members?

4 A. Given -- if -- if the PBMs were somehow to become  
5 aware of this and focus on this and see this at the same  
6 time that they would see this, they would also learn that  
7 they are benefitting themselves in certain ways from --  
8 from -- their profitability would go up to the extent that  
9 any kind of earnings they had were related to the increased  
10 AWP's, and how that sorted itself out with negotiations is  
11 anybody's guess.

12 Q. All right. So now I'm going to ask you to make a  
13 third assumption in light of your answer. I want you to  
14 assume that it does lead to the PBMs increasing the  
15 discounts and capturing some or all of that increased  
16 profit that the retailers have achieved due to the alleged  
17 5 percent scheme, all right. Do you have that third  
18 assumption?

19 A. Right.

20 Q. Would that likely lead to the PBM passing on to  
21 its client, the third-party payor, some or all of that  
22 profit that it captured?

23 MR. SOBOL: Objection to form.

24 THE WITNESS: There's -- there are so  
25 many if's in that hypothetical and so many

1 RAYMOND S. HARTMAN

2 things that would have to be dealt with and  
3 it is so unrelated to what -- the exercise  
4 that I've done here, that I haven't thought  
5 about it and I can't answer it.

6 MR. GOLDMAN: All right. I want to  
7 mark an excerpt from Professor Berndt's  
8 report. I have the whole report here if  
9 you want to see it.

10 (Exhibit 5, Berndt Report, marked for  
11 identification.)

12 Q. (By Mr. Goldman) Now, this is a -- Professor  
13 Berndt's report is something you're relying on, you said,  
14 correct, not all of it but portions of it, correct?

15 A. The portions that I've cited, I'm relying on.  
16 I've reviewed the report.

17 Q. Now, I want you to look at what we've marked as  
18 page 110. And again, if you want to see anything in front  
19 of or in back of my excerpt, just let me know, and I'll be  
20 happy to give you the full Berndt report.

21 A. Thank you.

22 Q. In fact, do you have a copy with you of the Berndt  
23 report?

24 A. God, no.

25 Q. Now, under A --

1 RAYMOND S. HARTMAN

2 A. I'm sorry. Let me just look at a little bit -- on  
3 what you did give me, let me look at 107 on. Okay. So I'm  
4 at page 110.

5 Q. Read -- no. Read as much as you want. Take your  
6 time.

7 A. Well, no. No. I wanted at least to read up to  
8 page 110. Why don't you ask me the question now. Oh, did  
9 you want to --

10 Q. Up to 110? It starts on 110, the excerpt. Do you  
11 have more than 110?

12 A. I have from page 107 on. I'm sorry.

13 Q. Well, I'm only starting with 110.

14 A. No wonder you were curious about why it was taking  
15 so long.

16 Q. No. It didn't hurt to read 107 to 110. No. It's  
17 from 110 on.

18 A. Okay. Well, I'm at 110 now, so I -- we can start  
19 here and --

20 Q. Do you want to read it or --

21 A. If I need to read beyond it, I'll let you know.

22 Q. Okay. I want to give you a chance to look at it  
23 if you want.

24 A. Well, okay. Let me take that chance. Okay.

25 Q. All right. So you've read this before, I take it?

1 RAYMOND S. HARTMAN

2 A. I have.

3 Q. And we are dealing under A it says on page 110,  
4 self-administered drugs, which is what our case is about,  
5 correct?

6 A. Correct.

7 Q. In 205, the first sentence, Professor Berndt said,  
8 "Both sides in this matter agree that the content of  
9 self-administered drugs, PBMs play a central role." Would  
10 you agree with that statement as well?

11 A. I would.

12 Q. If you see in 206, he's referring to an excerpt  
13 from an FTC, I think he said an opinion it looks like -- in  
14 any event, it's the FTC commenting on the transaction  
15 between two large PBMs, Care Market and AdvancePCS. Do you  
16 remember when that acquisition occurred?

17 A. I don't. It was -- you know, my guess is late  
18 '90s, early 2000s.

19 Q. And when it came out, did you happen to look at  
20 any of the FTC opinions regarding that transaction or  
21 acquisition?

22 A. I think I did in the context of the MDL matter,  
23 but I don't remember looking at it at the time of the --  
24 the acquisition and the FTC hearings.

25 Q. Do you recall learning that the FTC did approve

1 RAYMOND S. HARTMAN

2 that cost, I have -- I have not studied that --

3 Q. All right. Then let me ask you to assume. Assume  
4 that some contract between third-party payors and PBMs  
5 include provisions substantially as follows: In the event  
6 that the member purchases a brand name drug, the member  
7 will only be reimbursed with respect to that drug at the  
8 therapeutic equivalent generic price.

9 A. The --

10 MR. SOBOL: There's no question

11 before you.

12 Q. (By Mr. Goldman) Absent the doctor writing a  
13 prescription saying as stated. I want you to assume that  
14 there are contracts of that sort.

15 A. Okay. But I don't -- I still want to make sure I  
16 understand how you're defining the -- you're saying the  
17 patient is reimbursed. I'm thinking of a payment to the --  
18 there's a claim from a retail pharmacy that's part of a  
19 network with a PBM --

20 Q. Very good.

21 A. -- and so the claim is sent from the pharmacy to  
22 the TPP?

23 Q. I'm with you. So let me -- so the -- a TPP will  
24 only reimburse at the price of the generic therapeutic  
25 equivalent. Have you ever heard of that kind of provision?

1 RAYMOND S. HARTMAN

2 A. I have not -- that type of provision sounds like a  
3 plausible provision but I've not seen --

4 Q. Okay. I want you --

5 A. -- contracts that have effectuated that nor read  
6 about how many there might be.

7 Q. Well, do you know if, in fact, among the  
8 plaintiffs, that they have such a provision in their  
9 contracts?

10 A. I do not know.

11 Q. You didn't look to see; am I correct?

12 A. No, I did not.

13 Q. Because you didn't look at their contracts. Am I  
14 right?

15 A. That's correct.

16 Q. I want you to assume that these type of clauses  
17 exist in contracts between TPPs and PBMs. How would your  
18 formulaic methodology for computing aggregate damages  
19 address that?

20 A. The --

21 Q. Excuse me. It doesn't address it now; am I  
22 correct?

23 A. That's correct.

24 MR. SOBOL: Objection.

25 Q. (By Mr. Goldman) How would -- I'm sorry. How



1 RAYMOND S. HARTMAN

2 would you address it?

3 A. Well, the -- right now what my formulaic  
4 methodology addresses is any units that are sold and that  
5 are priced at AWP that are -- that the reimbursement rate  
6 -- the reimbursement for which is based on -- on AWP and  
7 the inflation caused thereby. Now, you're proposing an  
8 alternative, I take it, where some of those units are  
9 reimbursed at some other --

10 Q. Well, just the one as I explained, at the  
11 therapeutic generic equivalent price. How would you deal  
12 with it?

13 A. It is -- it's not something that has entered into  
14 the calculations and the methodology as it currently  
15 exists; and to the extent that that was something that had  
16 -- one would have to address the extent to which that does  
17 occur and those contracts prevail.

18 Q. How would you address the extent to which that  
19 occurred? Would you have to go out and ask each of the  
20 class members whether they have that provision?

21 A. Not having done it, I would have to look at that.

22 Q. So right now, no idea comes to mind as to how you  
23 would deal with that in your formulistic methodology for  
24 computing aggregate damages?

25 A. Nothing that I would want to propose as a

1 RAYMOND S. HARTMAN

2 few-minute break?

3 MR. GOLDMAN: Sure.

4 THE VIDEOGRAPHER: Here ends Tape 4.

5 Off the record 4:22 p.m.

6 (A brief recess was taken.)

7 THE VIDEOGRAPHER: Here begins Tape

8 Number 5. Back on the record 4:32 p.m.

9 Q. (By Mr. Goldman) With regard to the drugs on  
10 Appendix A in our case, do you know how many of them are  
11 multisource drugs which have therapeutic equivalents?

12 A. I have not studied that, no.

13 Q. Do you know whether all drugs are listed on  
14 Appendix A are covered by every one of the plans of  
15 third-party payors that are in the class?

16 A. That would be a study that would arise, I would  
17 argue, during the damage calculations, so I haven't yet  
18 attempted to ascertain that -- that detail.

19 Q. How would we go about finding out the answer?

20 A. I would have to determine that there -- there are  
21 publicly available sources of information about retail  
22 method of payment from places like IMS. There -- to the  
23 extent that I would look to other sources, I would have to  
24 address that at that stage.


25 Q. Does your formula address drugs that are not

1 RAYMOND S. HARTMAN  
2 COMMONWEALTH OF MASSACHUSETTS MIDDLESEX, SS.  
3

4 I, NICOLE E. GUILBERT, a Certified  
5 Shorthand Reporter and Notary Public duly  
6 commissioned and qualified in and for the  
7 Commonwealth of Massachusetts, do hereby  
8 certify that there came before me on the 4th  
9 day of October, 2006, at 9:46 a.m., the person  
10 hereinbefore named, RAYMOND S. HARTMAN, who  
11 provided satisfactory evidence of  
12 identification as prescribed by Executive  
13 Order 455 (03-13) issued by the Governor of  
14 the Commonwealth of Massachusetts, was by me  
15 duly sworn to testify to the truth and nothing  
16 but the truth of his knowledge concerning the  
17 matters in controversy in this cause; that he  
18 was thereupon examined upon his oath, and his  
19 examination reduced to typewriting under my  
20 direction; and that this is a true record of  
21 the testimony given by the witness to the best  
22 of my ability.

23 I further certify that I am neither  
24 attorney or counsel for, nor related to or  
25 employed by, any of the parties to the action  
in which this deposition is taken, and  
further, that I am not a relative or employee  
of any attorney or counsel employed by the  
parties hereto or financially interested in  
the action.

My Commission Expires: May 7, 2010

21  
22  
23  
24  
25  
  
Nicole E. Guilbert  
CSR/Notary Public

UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS

C.A. No.: 1:05-CV-11148-PBS  
Volume II  
Pages 279 to 397  
Exhibits: (See Index)

 **ORIGINAL**

-----  
NEW ENGLAND CARPENTERS HEALTH )  
BENEFITS FUND, PIRELLI ARMSTRONG )  
RETIREE MEDICAL BENEFITS TRUST; )  
TEAMSTERS HEALTH & WELFARE FUND OF )  
PHILADELPHIA AND VICINITY; and )  
PHILADELPHIA FEDERATION OF )  
TEACHERS HEALTH AND WELFARE FUND, )  
Plaintiffs, )  
 )  
-vs- )  
 )  
FIRST DATABANK, INC., a MISSOURI )  
CORPORATION, a Delaware Corporation. )  
Defendants. )  
-----

\* \* \* \* \*

DEPOSITION of DR. RAYMOND S. HARTMAN, called  
as a witness by and on behalf of the Defendants,  
pursuant to the applicable provisions of the  
Massachusetts Rules of Civil Procedure, before  
Lisa L. Gross, Registered Professional Reporter and  
Notary Public in and for the Commonwealth of  
Massachusetts, taken at the offices of Bonner,  
Kiernan, Trebach & Crociata, One Liberty Square,  
Boston, Massachusetts, on Thursday, October 5, 2006,  
commencing at 9:38 a.m.

1 DR. RAYMOND S. HARTMAN

2 evidence that I have seen, I have a good  
3 understanding of what the answer is going to  
4 be, but it's still worth asking it, and that  
5 would be subject to a liability analysis.

6 I have been asked to assume here, for  
7 purposes of what I'm doing, that they didn't  
8 know, and that they didn't respond, and that  
9 they were locked in for reasons that are  
10 facially accurate to me.

11 Q. So, now I want to ask you, if I used  
12 your formulistic methodology, and as set forth  
13 on pages 11 and 12 of your declaration, do you  
14 know how it would compare to the actual  
15 damages of any of these individual  
16 plaintiff's, how close would I come to their  
17 actual damages?

18 A. When the time came to implement the  
19 damage analysis, I would do it in several  
20 different ways. I would no doubt implement  
21 Equation (1A). There's a variation of using  
22 the data in paragraph 21 that would merely  
23 give me a percentage of the total amounts paid  
24 by third-party payor's, where it doesn't even  
25 require a 15 percent or 18 percent, whatever

1 DR. RAYMOND S. HARTMAN

2 it is, it's just a percentage of what they  
3 reimburse.

4 And I would look at the accuracy of  
5 the data that's reported -- that I would be  
6 basing that on, which would be IMS data, which  
7 is a very reputable data source. And I would  
8 look at the results and determine whether those  
9 are --

10 Q. Sure.

11 A. -- reasonable.

12 Q. But let's see if you can answer my  
13 question. As you sit here today, can you tell  
14 me, if I used your formulistic methodology set  
15 forth on pages 11 and 12 to compute damages  
16 for the named Plaintiffs', how close would I  
17 come to what their actual damages are; do you  
18 know?

19 MR. SOBOL: Objection to the form.

20 A. I have not applied this to the named  
21 Plaintiffs'. I'm talking -- right now, I'm  
22 talking about an aggregate level of damages.  
23 We have pursued some hypotheticals about  
24 individuals, but this is not something that  
25 I'm being asked to do at an individual level

1 DR. RAYMOND S. HARTMAN

2 now.

3 I have been asked to calculate  
4 aggregates, class one damages. I proposed one  
5 method. There's other methods that are -- that  
6 as I was reviewing the data I thought were more  
7 accessible and easier to implement.

8 And at the time of the damage  
9 analysis, if I'm asked to do an allocation or  
10 some kind of a -- some claims administration  
11 calculation for individuals, I will do that,  
12 but -- and I have done that in the past and  
13 it's been accurate enough to be accepted by  
14 courts in the past. But I have not done that  
15 now, nor have I been asked to.

16 Q. So, therefore, you don't know whether  
17 using your formulistic methodology for the  
18 named Plaintiffs' would result in overstating  
19 or understating their damages; am I correct?

20 MR. SOBOL: Objection the form.

21 A. It's my opinion, based on the work that  
22 I have done, that it will be an accurate and  
23 reasonable estimate of their damages.

24 Q. So you believe, using your formulistic  
25 methodology, we will come within five percent

1 DR. RAYMOND S. HARTMAN

2 of their actual damages plus or minus five  
3 percent?

4 MR. SOBOL: Objection to form.

5 A. I'm not stating confidence intervals.

6 I'm saying it will be a reasonable  
7 enough calculation and estimate of damages for  
8 the purposes of this litigation.

9 Q. Well, what will you use -- what's your  
10 standard for reasonableness, plus or minus  
11 five percent?

12 MR. SOBOL: Objection to the form.

13 Q. Well, let me be clear. When I say plus  
14 or minus, that the methodology will produce  
15 damages which come within five percent more or  
16 five percent less than actual damages of the  
17 Plaintiffs', that's what I'm getting at, do  
18 you have confidence in that?

19 MR. SOBOL: Objection to the form.

20 A. I am generally not asked to calculate  
21 confidence intervals for the aggregate  
22 damages, nor is it generally asked of me by  
23 counsel or by courts.

24 Q. Now, I would give you the errata sheet  
25 from yesterday. But I'm embarrassed to say



1 DR. RAYMOND S. HARTMAN

2 formula.

3 Q. But in the example you gave, that's 15  
4 percent?

5 A. It is later.

6 Q. And what is "DF"?

7 A. "DF" is the dispensing fee.

8 Q. Now, here's my question: Why is it, and  
9 tell me in as fulsome detail as you are  
10 able --

11 A. Fulsome?

12 Q. As -- all that you can think about.  
13 That's a legal term.

14 A. Fulsome means very smelly.

15 Q. I'm just used to using it as a lawyer,  
16 Dr. Hartman. I would like to get your best  
17 shot.

18 A. It's also a prison.

19 Q. That's Folsom. So I would start again.

20 And serious here. I would like to  
21 have you tell me all of the reasons why you  
22 believe "P" and "DF" should remain unaffected  
23 by the Scheme in your formula.

24 A. I've been -- I have taken that as an  
25 assumption, and an assumption that is facially

1 DR. RAYMOND S. HARTMAN

2 confirmed by everything that I have seen in  
3 this market, and all the analysis that I have  
4 seen in this market. And now what I'm saying  
5 -- well, yeah. Period.

6 Q. All right. So have you done a study  
7 that confirms your view of the industry that  
8 in your formula P and DF should remain  
9 unaffected by the Scheme?

10 A. I have not done that study for putting  
11 forward this formulation.

12 Q. Now, if that were incorrect, if P and DF  
13 were variables because of the five percent,  
14 alleged five-percent Scheme, would it be  
15 correct that the formula that you have here  
16 would not be usable to arrive at aggregates  
17 damages on a formulaic basis?

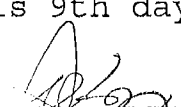
18 A. If, contrary to all evidence I have seen  
19 in this matter, the distribution of PA,  
20 distribution of "P" across third-party payor's  
21 and the level of DF both its amount and  
22 average changed, then as part of the damage  
23 analysis I would -- I would corroborate  
24 whether it has remained the same. I would  
25 corroborate the assumptions that I have made

## C E R T I F I C A T E

I, Lisa Lee Gross, Registered Professional Reporter and Notary Public duly commissioned and qualified in and for the Commonwealth of Massachusetts, do hereby certify that there came before me on the day 5th of October, the person hereinbefore named, who was by me duly sworn to testify to the truth and nothing but the truth of their knowledge touching and concerning the matters in controversy in this cause; that they were thereupon examined upon their oath, and their examination reduced to typewriting under my direction and that the deposition is a true record of the testimony given by the deponent.

I further certify that I am neither attorney nor counsel for, nor related to or employed by, any of the parties to the action in which this deposition is taken, and further that I am not a relative or employee of any attorney or counsel employed by the parties hereto or financially interested in this action.

In Witness Whereof, I have hereunto set my hand and affixed my seal this 9th day of October, 2006.

  
\_\_\_\_\_  
Notary Public  
My Commission Expires:  
January 17, 2011

# **Exhibit 13A**

Carol Sidwell

Moline, IL

September 17, 2004

Page 1

1                   IN THE UNITED STATES DISTRICT COURT  
2                   FOR THE DISTRICT OF MASSACHUSETTS  
3  
4   IN RE PHARMACEUTICAL                   )  
5   INDUSTRY AVERAGE WHOLESALE   )   MDL No. 1456  
6   PRICE LITIGATION                   )   Civil Action: 01-CV-12257-PBS  
7   THIS DOCUMENT RELATES TO           )  
8   ALL CLASS ACTIONS                   )

9

10               Deposition of CAROL SIDWELL, taken before  
11   GREG S. WEILAND, CSR, RMR, CRR, Notary Public,  
12   pursuant to the Federal Rules of Civil Procedure for  
13   the United States District Court pertaining to the  
14   taking of depositions, at Suite 300, 1630 Fifth  
15   Avenue, in the City of Moline, Illinois, commencing  
16   at 10:38 o'clock a.m., on the 17th day of September,  
17   2004.

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Carol Sidwell

Moline, IL

September 17, 2004

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1 less 14.5 percent or the U&C; is that correct?

2 A. Yes.

3 Q. The question is, what is the explanation  
4 for the different rates reflected in these two  
5 contracts?

6 A. Our competitive rates in Tennessee are  
7 much different than in the Iowa and Illinois area as  
8 is our distribution of membership, so we were able  
9 to because of our volume, because of our  
10 longstanding business relationship get a more  
11 favorable reimbursement from Walgreens than what we  
12 are from a pharmacy in Tennessee.

13 Q. What does John Deere do, if anything, to  
14 monitor its prescription drug program costs?

15 A. We monitor claims processed on a daily  
16 basis. We have weekly, monthly, quarterly reporting  
17 that looks at our claim volume, our cost per claim,  
18 brand generic utilization, formulary. We have  
19 various employer group reporting, various segments  
20 of our population looking at trends.

21 It would be easier to say what we don't do  
22 to monitor it.

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September 17, 2004

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1 overall percentage, it may have been.

2 Q. Okay. And talking now exclusively of  
3 brand name drugs here, was it ever 4 percent, just a  
4 ballpark estimate?

5 A. I don't feel prepared to answer that  
6 without the facts and data. Certainly I would  
7 expect it to be in about that range.

8 Q. Okay. You also testified as to your  
9 understanding of AWP or average wholesale price and  
10 that you believed it was something of a sticker  
11 price, like an MSRP on a car.

12 A. Yes.

13 Q. Exploring your understanding of AWP a  
14 little further, do you know who determines the AWP?

15 A. My understanding is that it's set by the  
16 manufacturers, sometimes in conjunction with other  
17 entities, that there isn't really an AWP. For  
18 example, if I use First Data Bank, who I use in my  
19 pharmacy processing as my source for AWP, it is  
20 different than if I use Redbook as my source for  
21 AWP.

22 I don't know the various components that

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1 go into who sets the specific AWP level.

2 Q. Okay. Now, can you explain a little  
3 further, just focusing on the terms AWP, average  
4 wholesale price, what do you understand it to be  
5 representative of?

6 MR. HAAS: Objection to form.

7 THE WITNESS: My understanding of AWP is  
8 that it's strictly a reference price. I don't know  
9 that I would say that it's representative of -- I  
10 don't have a good definition of that. It's my  
11 reference price that I use as a benchmark to price  
12 drugs from that.

13 BY MS. MacMENAMIN:

14 Q. Okay. Now, you testified that wholesale  
15 acquisition cost as you understand it is a price  
16 paid by wholesalers to manufacturers.

17 Now, you understand AWP, average wholesale  
18 price, to be a price charged by wholesalers or an  
19 average of prices charged by wholesalers?

20 MR. HAAS: Objection to form.

21 THE WITNESS: I don't believe that my  
22 wholesale -- I guess I would like to refer back to



Carol Sidwell

Moline, IL

September 17, 2004

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1 that affect your negotiations with pharmacies in  
2 using AWP as a benchmark?

3 MR. HAAS: Objection to form.

4 THE WITNESS: I guess I already understand  
5 that AWP is not necessarily a direct linear  
6 relationship to the cost or the price that that  
7 pharmacy pays for the drug, so since I know that  
8 today, I'm not sure that it would change the way I'm  
9 doing business or the way I'm contracting with my  
10 pharmacies.

11 BY MS. MacMENAMIN:

12 Q. In your negotiations with manufacturers  
13 for rebates and discounts, are those negotiations  
14 also based on the benchmarks AWP and WAC?

15 A. Those are certainly two of the things that  
16 are used to calculate the various levels of rebates.

17 Q. Can you tell me of any other benchmarks  
18 that are available?

19 A. I look at the other costs of drugs in that  
20 class based on AWP, based on WAC, and based on the  
21 rebate amounts that the other manufacturers are  
22 willing to offer to get down to a net price.

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Moline, IL

September 17, 2004

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1           So regardless of -- to me it's a  
2   mathematical calculation of what is the lowest net  
3   cost. Whether it's a lower AWP and then a lower  
4   rebate or whether it's a higher AWP and a bigger  
5   rebate, we're worried about the net cost line.

6           Q.    Okay. You just said earlier that most of  
7   your negotiations with manufacturers are based on  
8   WAC and that some of them are based on AWP, and in  
9   conjunction with your testimony that WAC is somewhat  
10  representative of the price wholesalers pay to  
11  manufacturers, my question is, if you found out and  
12  if you learned that wholesalers paid significantly  
13  less than WAC, would that affect your negotiations  
14  for rebates with manufacturers?

15          A.    Again, I believe that wholesale  
16  acquisition cost is a reference point. I'm not sure  
17  it's exactly what wholesalers purchase their drugs  
18  for. I'm sure there are other margins in there.

19                But no, it's not going to impact the way  
20  that I negotiate with manufacturers.

21          Q.    My question was that it being a reference  
22  point, if you found out that WAC was significantly

Carol Sidwell

Moline, IL

September 17, 2004

Page 82

1 STATE OF ILLINOIS )  
2 ) SS:  
3 COUNTY OF C O O K )

4 The within and foregoing deposition of the  
5 witness, CAROL SIDWELL, was taken before GREG S.  
6 WEILAND, CSR, RMR, CRR, Notary Public, at Suite 300,  
7 1630 Fifth Avenue, in the City of Moline, Illinois,  
8 commencing at 10:38 o'clock a.m., on the 17th day of  
September, 2004.

9 The said witness was first duly sworn and was  
then examined upon oral interrogatories; the  
10 questions and answers were taken down in shorthand  
by the undersigned, acting as stenographer and  
11 Notary Public; and the within and foregoing is a  
12 true, accurate and complete record of all the  
13 questions asked of and answers made by the  
14 aforementioned witness at the time and place  
15 hereinabove referred to.

16 The signature of the witness was waived by  
17 agreement of counsel.

18 The undersigned is not interested in the  
19 within case, nor of kin or counsel to any of the  
20 parties.

21 Witness my official signature and seal as  
22 Notary Public in and for Cook County, Illinois, on

Carol Sidwell

Moline, IL

September 17, 2004

Page 83

1 this 20th day of September, 2004.

2

3

4

GREG S. WEILAND, CSR, RMR, CRR

5

License No. 084-003472

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# **Exhibit 16A**

JAMES W. BUCKLEY, JR.

UNITED STATES DISTRICT COURT

DISTRICT OF MASSACHUSETTS

 ORIGINAL

- - - - - X

NEW ENGLAND CARPENTERS HEALTH

BENEFITS FUND, et al.,

Plaintiffs,

v.

Civil Action

FIRST DATABANK, INC., and

No. 1:05-CV-11148-PBS

McKESSON CORPORATION,

Defendants.

- - - - - X

VOLUME I

Pages 1-201

VIDEOTAPED DEPOSITION OF JAMES W. BUCKLEY, JR.,  
a witness called by counsel for the Defendant,  
McKesson Corporation, taken before Kimberly A Smith,  
Certified Realtime Reporter, Registered Diplomate  
Reporter, and Notary Public in and for the  
Commonwealth of Massachusetts, at the Law Offices of  
Bonner, Kiernan, Trebach & Crociata, LLP, One Liberty  
Square, Boston Massachusetts 02109, on Friday,  
October 20, 2006, commencing at 9 34 a.m.

1 JAMES W. BUCKLEY, JR.

2 A. I and II are the active plans, yes.

3 Q. So if I refer to it as the active plans --

4 A. I and II.

5 Q. -- you'll understand that I'm talking about  
6 I and II?

7 A. Yes.

8 Q. So under the current prescription drug  
9 plans for active members, are there any generic caps?

10 A. No. But in the State of Massachusetts,  
11 it's required to dispense generic unless otherwise  
12 stated.

13 Q. When you say, "It's required to dispense  
14 generic unless otherwise stated," you're referring  
15 to --

16 A. The physician.

17 Q. -- if the physician doesn't specify a brand  
18 and there's a generic equivalent, your understanding  
19 is the generic has to be prescribed?

20 A. Would be dispensed.

21 Q. Would be dispensed. Thank you.

22 Does your member have the ability to  
23 request the brand even if the physician hadn't  
24 specified it?

25 A. The member -- the member could make a phone

1 JAMES W. BUCKLEY, JR.

2 call to the physician; and if the physician is  
3 willing to write a -- write the script and it says  
4 "as written," the member would be getting the brand.

5 Q. Right. But unless the physician has  
6 specified to be dispensed as written, it's your  
7 understanding that the pharmacist is not allowed to  
8 dispense the brand if a generic equivalent is  
9 available?

10 A. If the member at that point -- if there is  
11 no script from the physician saying "dispense as  
12 written" and the member would like the brand name,  
13 the member will pay the difference between the  
14 generic and the brand.

15 Q. So -- and just to use an example to  
16 illustrate, if the brand was \$50 for the prescription  
17 and the generic was \$10, in your example -- or using  
18 that example in the situation you just described,  
19 then your member would pay the difference between  
20 \$10 and \$50; is that your understanding?

21 A. If -- if he wanted the brand, yes.

22 Q. Does the current plan for active members  
23 include any -- I'm sorry -- exclude any prescription  
24 drugs?

25 A. The answer is yes. And for the most part,



1 JAMES W. BUCKLEY, JR.

2 AFTERNOON SESSION

3 (1:34 p.m.)

4 THE VIDEOGRAPHER: We're back on the  
5 record. This marks the beginning of Videotape No. 3  
6 in the deposition of James W. Buckley. The time is  
7 1:35.

8 JAMES W. BUCKLEY, JR.,  
9 the witness at the time of recess, having  
10 been previously duly sworn, was further  
11 deposed and testified as follows:

12 EXAMINATION (continued)

13 BY MR. FLUM:

14 Q. Welcome back, Mr. Buckley.

15 A. Thank you.

16 Q. We had been talking before the lunch break  
17 about the PBM agreements between the New England  
18 Carpenters Fund and AdvancePCS. I wanted to continue  
19 looking at PBM agreements that were entered into  
20 after that.

21 A. Okay.

22 Q. So do you recall that the -- that the fund  
23 entered into a PBM contract with Ullico?

24 A. Ullico Medco?

25 Q. Yes

1 JAMES W. BUCKLEY, JR.

2 A. Yes.

3 Q. And that was pursuant to -- Well, let me  
4 back up.

5 So we talked about this a little bit.  
6 Ullico Medco is, for want of a better phrase --

7 A. It's somehow affiliated with Medco.

8 Q. And it's -- but it's --

9 A. It more or less is -- it deals with more of  
10 their Taft-Hartley clientele, but it -- but that  
11 doesn't mean that Medco couldn't do the same thing.  
12 To this day, I still don't understand why they  
13 competed against one another when they were the same  
14 company. So I don't have an answer for you.

15 Q. Well, let me actually ask you a question  
16 because I was going to ask you something a little bit  
17 different. Ullico Medco contracts with the National  
18 Labor Alliance of Health Care Coalitions, correct?

19 A. Ullico Medco has a -- Because of an  
20 affiliation we have with the Massachusetts coalition,  
21 which is affiliated with the national coalition, we  
22 ended up getting better pricing through Ullico Medco.

23 Q. Let me go back because I'm just trying --  
24 I'm just trying to understand how the relationship  
25 works

1 JAMES W BUCKLEY, JR.

2 A. Yes. We went through this the other day.  
3 This is really --

4 Q That's fine. It will work better if you  
5 let me ask questions and you answer them. When the  
6 New England Teamsters fund contracted with Ullico  
7 Medco -- First of all, do you remember that was in  
8 2005?

9 A Yes

10 Q So when you entered into that contract, did  
11 you contract directly with Ullico Medco, or did you  
12 come in under an umbrella master agreement that  
13 Ullico Medco had with another organization?

14 A. We negotiated a contract directly with  
15 Ullico Medco.

16 Q And then the service that you obtained  
17 pursuant to that contract was covered by the terms of  
18 a master agreement with a -- with the National Labor  
19 Alliance of Health Care Coalitions?

20 A That's correct

21 Q So let me show you a couple documents to  
22 make sure that we're all -- we're talking about the  
23 same thing

24 What are we up to?

25 THE COURT REPORTER: 8

1 JAMES W. BUCKLEY, JR.

2 MR. FLUM: Mark that as Exhibit 8, please.

3 (N.E. Carpenters Exhibit No. 8  
4 was marked for identification.)

5 BY MR. FLUM:

6 Q. For the record, what the court reporter has  
7 marked as Exhibit 8 is a copy of a document produced  
8 by New England Carpenters in this case. It bears  
9 Production Nos. CARP 59 through 88, correct?

10 A. Yes.

11 Q. And can you tell me what this document is?

12 A. It says it's an executed copy of the  
13 prescription drug program master agreement.

14 Q. So is this the agreement that sort of is  
15 the umbrella that sits over the agreement between New  
16 England Carpenters and Ullico Medco that became  
17 effective in 2005?

18 A. Yes.

19 Q. And am I correct that the terms set out in  
20 this master agreement, at least the economic terms  
21 Well, let me back up.

22 Am I correct that the terms of the  
23 master agreement are the terms that govern New  
24 England Carpenters' 2005 agreement with Ullico Medco?

25 A. With respect to what?

1 JAMES W. BUCKLEY, JR.

2 Q. With respect to the prescription drug  
3 program.

4 A. Only with respect to the pricing. Because  
5 if you look at this document, we never executed this  
6 document.

7 Q. I understand. So when you say "only with  
8 respect to the pricing," what other document then  
9 governs the terms of the New England Carpenters 2005  
10 agreement with Ullico Medco?

11 A. What happened with the document for the  
12 agreement with Ullico Medco and the New England  
13 Carpenters Health Benefits Fund, it got snagged down  
14 with attorneys with respect to the indemnification  
15 clause. And we never executed a contract. We only  
16 executed a document for financial reimbursement and  
17 how claims were going to be paid. And what the fee  
18 structure was, there was never a document executed.

19 Q. So there was a document that was produced  
20 to us called a member fund addendum, and it's  
21 unsigned. I'm going to have the court reporter mark  
22 that as next in order.

23 (N.E. Carpenters Exhibit No. 9  
24 was marked for identification.)

25

1 JAMES W. BUCKLEY, JR.

2 BY MR. FLUM:

3 Q For the record, Exhibit 9 is a document  
4 produced by New England Carpenters in this case.  
5 It's got Production Nos. CARP 89 to 90 on it. And I  
6 take it from your last answer that this member fund  
7 addendum that we've marked as Exhibit 9 was never  
8 signed?

9 A I believe that's correct

10 Q So you -- Is it your understanding that  
11 Ullico Medco was providing services to New England  
12 Carpenters pursuant to the economic terms that are  
13 laid out in Exhibit 8 even though you never signed an  
14 agreement to that effect?

15 A We only -- We only -- I believe we only  
16 executed probably a couple pages dealing with the  
17 financial -- the financials, not any of the document  
18 because the document was never completed.

19 Q Did you -- Well, let me follow up on that.

20 A Sure.

21 Q Are you saying you signed a document with  
22 Ullico Medco that governed the terms of the 2005 PBM  
23 contract?

24 A With respect to monetary disbursements,  
25 yes. And then subsequent to that -- I'm going to

1 JAMES W. BUCKLEY, JR.

2 give you a short version of this, okay? What -- We  
3 originally negotiated a contract with Ullico Medco.  
4 Because of our affiliation with the Massachusetts  
5 coalition, okay, which is this document that --  
6 executed document here that you're showing me, within  
7 the terms of that document, if the number grew, okay,  
8 with the participation, there was an automatic  
9 reduction in fees with anybody affiliated with that.

10 So we initially executed a document  
11 with Medco -- Ullico Medco for reimbursement,  
12 administration, whatever. And subsequent to that,  
13 because of our affiliation with -- because Ullico  
14 Medco wasn't aware that we were part of the  
15 Massachusetts coalition and subsequently we were part  
16 of this arrangement, there was reduced fees that came  
17 with this. But we never executed a contract with  
18 Medco. We just initially executed a fee schedule  
19 with Medco -- Ullico -- let me -- Ullico Medco.

20 Q. When you say you executed a fee schedule,  
21 there's an actual document that sets the fees out  
22 that governed the relationship between your fund and  
23 Ullico Medco during nineteen -- or during 2005 that  
24 you signed and that Ullico Medco signed?

25 A. That was executed by the fund. I'm not

1 JAMES W. BUCKLEY, JR.

2 sure if I signed it, but it was executed by the fund.

3 MR. FLUM: I don't believe that's been  
4 produced.

5 MR. NOTARGIACOMO. We haven't --

6 Can we go off the record?

7 MR. FLUM: All right. Let's go off the  
8 record.

9 THE VIDEOGRAPHER: Going off the record.  
10 The time is 1:45.

11 (Recess at 1:45 p.m.,  
12 resumed at 1:46 p.m.)

13 THE VIDEOGRAPHER. We're back on the  
14 record. The time is 11:47.

15 THE COURT REPORTER: No.

16 THE VIDEOGRAPHER: I'm sorry. 1:47.

17 MR. FLUM: You're making the witness  
18 nervous

19 BY MR. FLUM:

20 Q. Mr. Buckley, we had a discussion off the  
21 record about the executed agreement between the fund  
22 and Ullico Medco. And I think suffice it to say that  
23 as of today, neither your counsel nor I have seen it

24 A. Okay

25 Q So we're going to I'm going to ask that



1 JAMES W. BUCKLEY, JR.

2 you have your files -- search for that, and hopefully  
3 it will turn up and we'll be able to look at it when  
4 we reconvene in November.

5 A. That's fair.

6 Q Now, the agreement that we marked as  
7 Exhibit 8 -- that's the master agreement with the  
8 National Labor Alliance and Medco -- does contain  
9 some economic terms. I'd like you to take a look, if  
10 you would, at page 15 of that agreement. And it's  
11 marked as Exhibit 8. This is a Schedule A, "Program  
12 Pricing Terms."

13 Do you see that?

14 A. Yes, I do.

15 Q And do you see that under the "Retail  
16 Pharmacy Program Claims" heading, there's pricing  
17 there that's identified as -- actually there's  
18 several alternatives, and one of them is "AWP minus  
19 15 1/2 percent, plus the dispensing fee set forth  
20 below."

21 Do you see that?

22 A. Yes.

23 Q So is that the pricing that the fund was  
24 getting from Ullico Medco?

25 A. It was the final document that was

1 JAMES W. BUCKLEY, JR.

2 revamped because of us joining this organization,  
3 then I will say yes to this. If it's not, then I  
4 don't know. Because as I said to you earlier,  
5 because of our numbers joining the Massachusetts and  
6 the national alliance, that through the arrangement  
7 the international had with Ullico Medco, the fees  
8 would be reduced based on the number of participants.  
9 So I'm not trying to avoid your question. I'm being  
10 honest with you.

11 Q. So it's -- The short answer -- or is a fair  
12 characterization of what you just said "I don't  
13 know"?

14 A. I don't know. I don't know.

15 Q. Is there correspondence back and forth  
16 between the fund and anyone else that would document  
17 the discussions about getting that better pricing --

18 A. No.

19 Q. -- from Ullico Medco?

20 A. The answer is no. And one -- These  
21 documents -- This document here and subsequently the  
22 other one, which I believe is -- 2002 is the date on  
23 this Is there another one like this?

24 Q. Well, this one -- When you say "this one,"  
25 are you talking about Exhibit 8?

1 JAMES W. BUCKLEY, JR.

2 A No.

3 Q. No.

4 A. I think there's another one of these that  
5 has a different date on it.

6 Q. I have seen a couple of different  
7 versions --

8 A Okay.

9 Q. -- of the master agreement. I think  
10 there's one -- I want to say 2003 and I believe  
11 there's also one from 2006.

12 A. Maybe it was 2003, that -- Before  
13 yesterday, I hadn't seen these before, these  
14 documents.

15 Q. "These documents" being the master  
16 agreements?

17 A. That's correct. And the only reason that I  
18 think it got produced is I do not believe it came  
19 from Lois or Rusty. I think it came from Harry's  
20 secretary, Margaret. Because when we were looking  
21 around for documentation, I believe I asked her, and  
22 that's where these came from. But --

23 Q. Harry is who?

24 A. Harry Dow is the executive director of the  
25 New England Carpenters Health Benefit -- I mean, the

1 JAMES W. BUCKLEY, JR.

2 combined board.

3 Q. The combined board of what?

4 A. Which is the New England Carpenters --  
5 combined board is the title for all the funds, which  
6 is the pension fund, the annuity fund, health fund.  
7 So --

8 Q Including the prescription drug benefit?

9 A Which is -- which is in the health fund,  
10 that's correct

11 Q. I understand So we'll just -- we'll come  
12 back to that hopefully when we have some more  
13 documents that shed further light.

14 MR. NOTARGIACOMO: Just to follow up on  
15 what the witness testified to, there is one master  
16 agreement that is dated 2002 that was provided this  
17 morning. That's what I was trying to tell you at the  
18 break.

19 MR. FLUM: Well, then there are three  
20 others, because there's also one from 2003 that Segal  
21 produced.

MR. NOTARGIACOMO: Oh, I see

MR. FLUM: So I'm not sure that --

24 MR. NOTARGIACOMO: That I'm unaware of

25 THE WITNESS: And I'm unaware of that also,

1 JAMES W. BUCKLEY, JR.

2 okay? So that's...

3 MR. FLUM: So I'm not sure that any of that  
4 is going to help us get to an answer right now.

5 THE WITNESS: Okay.

6 MR. FLUM: I just want to clarify,  
7 Mr. Notargiacomo, when you're talking about an  
8 agreement dated 2002, is it an agreement that's  
9 entered into the 1st day of January 2003?

10 MR. NOTARGIACOMO: Oh, you're right. I'm  
11 sorry. Yes, I'm sorry. I misspoke. You're right.  
12 It is January 2003.

13 MR. FLUM: So maybe we've eliminated one...

14 MR. NOTARGIACOMO: Eliminated one? Okay.

15 MR. FLUM: While we're on this, why don't  
16 we mark this -- What are we up to? 10?

17 THE COURT REPORTER: Um-hum.

18 (N.E. Carpenters Exhibit No. 10  
19 was marked for identification.)

20 BY MR. FLUM:

21 Q. So for the record, what we've marked as  
22 Exhibit 10 is a document that counsel handed me this  
23 morning. This was just prior to the deposition.  
24 There are no production numbers on it, but I  
25 understand it comes from New England Carpenters'

1 JAMES W. BUCKLEY, JR.

2 files.

3 It's a multipage document entitled  
4 "Integrated Prescription Drug Program Management  
5 (sic) Agreement," and it shows that -- or it states  
6 in the first line that "This agreement is entered  
7 into as of the 1st...of January 2003."

8 Mr. Buckley, have you seen Exhibit 10  
9 before today?

10 A. Only yesterday.

11 Q. That was the first time?

12 A. That's correct.

13 Q. And I take it you don't know whether  
14 Exhibit 10 governed the terms of the relationship  
15 between New England Carpenters and Ullico Medco in  
16 2005?

17 A. The answer is no.

18 Q. You don't know?

19 A. I don't know because all I know is that  
20 I -- that the original fee structure, that it was  
21 changed -- use of the affiliation with the Mass. and  
22 also the international agreement, that change with  
23 Ullico Medco. It enhanced the fee structure.

24 Q. Did you ever see a copy of an agreement,  
25 a master agreement, with the enhanced fee structure

1 JAMES W. BUCKLEY, JR.

2 between Medco and the United Brotherhood of  
3 Carpenters and Joiners?

4 A. I do not believe so. I -- as I stated  
5 earlier, we never executed the document. I believe  
6 there was only a fee structure executed. I'm not  
7 sure why we don't have it. And we've talked about  
8 that. I'm going to look to find that, but...

9 Q. Well, let me come at it this way.

10 A. Okay

11 Q. In 2006, in this year --

12 A. Okay.

13 Q. -- did the fund enter into a new PBM  
14 agreement with some affiliate of Medco that provided  
15 better discounts, larger discounts off AWP than the  
16 fund had been receiving?

17 A. As of -- I believe the date is June of  
18 2006, okay? -- we entered into an agreement with the  
19 International Brotherhood -- the International  
20 Carpenters and Brothers and Joiners of America (sic)  
21 through -- PSG, which is a consulting firm, went out  
22 and sent out RFPs to all the large PBMs because our  
23 international president, Doug McCarron, wanted to  
24 have one prescription plan for the whole brotherhood  
25 across the country. So they negotiated a deal.

1 JAMES W. BUCKLEY, JR.

2 It was -- I went to a meeting, I  
3 believe, in -- I think I went to a meeting in 2004.  
4 And it took us a while before we executed the  
5 contract. It was presented to me at this meeting  
6 that the fund would save \$700,000 by entering into  
7 the agreement through Medco directly through the  
8 affiliation through our international.

9 I brought that information back to  
10 the fund. It was presented to Segal. Segal had  
11 numerous conversations with the consulting firm PSG,  
12 comparing numbers, and I think it was in 2006 or 2005  
13 we entered into that agreement because Segal came  
14 back to the board and informed the board that we  
15 would save \$400,000 by entering into this agreement.

16 MR. FLUM: Why don't we mark this one as...

17 THE WITNESS: What was the date on that one  
18 because I --

19 MR. NOTARGIACOMO: Let him ask questions.

20 MR. FLUM: Are we up to 11?

21 THE COURT REPORTER: Yes

22 (N.E. Carpenters Exhibit No 11  
23 was marked for identification.)

24 BY MR. FLUM:

25 Q Now, sir, this is what I've marked as



1 JAMES W. BUCKLEY, JR.

2 Exhibit 11 -- what the court reporter has marked --  
3 is a document that was produced by Segal, I  
4 understand. We actually got it from your counsel  
5 about 4:00 o'clock yesterday afternoon. And I  
6 understand that Segal had given it to your lawyers  
7 and they then provided copies to us. This one bears  
8 Production Nos. Segal-Carpenter 3056 through 3112.

9 And my question to you is whether  
10 this is the master agreement between Medco and the  
11 United Brotherhood of Carpenters and Joiners of  
12 America that governs the current PBM contract that  
13 the fund has with Medco?

14 A. Yes.

15 Q. So I'd like you to take a look at -- just  
16 on the first page. There's a heading that says  
17 "Definitions," and then paragraph 1.1 below that has  
18 got the word "AWP" in bold and in quotes.

19 Do you see that?

20 A. Yes

21 Q. And do you see that this agreement, the UBC  
22 master template says that "'AWP' means the average  
23 wholesale price of the covered drug as of the  
dispensing date as set forth in the then current  
price list of First DataBank's national drug data

1 JAMES W. BUCKLEY, JR.

2 file," correct?

3 A. Yes.

4 Q. So you understand that under this master  
5 agreement that -- pursuant to which the fund is  
6 obtaining PBM services, "AWP" is defined as being the  
7 price that is published by First DataBank, correct?

8 A. That's what it says, yes.

9 Q. Now, you've sued McKesson and First  
10 DataBank because you believe that price has been  
11 manipulated, correct?

12 A. Yes.

13 Q. Did you object to entering into a contract  
14 that was tied to the First DataBank price?

15 A. At the time we didn't negotiate this  
16 contract. It was -- it came from our international.  
17 The arrangements in the contract were better than  
18 what we currently had with Ullico Medco There was  
19 an additional \$400 savings.

20 And at that time everybody was  
21 dealing with First DataBank as far as AWP, so we had  
22 no alternative to enter an agreement and save the  
23 money for the fund both through the new contract and  
24 the arrangement. So yes, we did enter into this  
25 agreement.

1 JAMES W. BUCKLEY, JR.

2 Q. And you didn't object to using First  
3 DataBank pricing, correct?

4 A. First DataBank pricing was the only pricing  
5 out there. They establish AWP.

6 Q. So if you continue reading down into this  
7 paragraph 1.1, a little bit more than halfway down  
8 there's a sentence that starts out, "If First  
9 DataBank or other applicable source."

10 Do you see that?

11 A. Yes.

12 Q. And that sentence in its entirety reads,  
13 "If First DataBank or other applicable source changes  
14 the methodology for calculating AWP or pricing for  
15 covered drugs in a way that materially changes the  
16 economics of the program, the parties shall negotiate  
17 in good faith to modify the program pricing terms to  
18 preserve the parties' relative economics before such  
19 changed methodology."

20 Do you see that?

21 A. Yes.

22 Q. Now, do you understand that there's a  
23 proposed settlement between the class that your fund  
24 is seeking to represent and First DataBank?

25 A. There was a newspaper article. I believe

1 JAMES W. BUCKLEY, JR.

2 it came out in the Wall Street Journal.

3 Q. Has the fund approved the terms of that  
4 settlement?

5 A. I don't know whether it's been -- I believe  
6 that information was brought to the board, and we  
7 left it in the hands of the attorneys.

8 Q. Do you know whether the board has approved  
9 the terms of the proposed settlement?

10 A The answer is -- I believe they have.

11 Q. And what -- what do you understand the key  
12 provisions are of the proposed settlement with FDB?

13 A Based on what I read out of the newspaper  
14 article is that I believe First DataBank is going to  
15 go out of -- going to stop publishing AWP after two  
16 years, providing there's no other -- there's no  
17 other -- there's no other AWP out there, something to  
18 that effect I don't remember exactly what was in  
19 the article, but something to that effect.

20 Q. Do you remember learning that under the  
21 terms of the proposed settlement, there would be a  
22 period during which AWP would roll back the published  
23 levels of AWP?

24 A. Yes. That was in the article also. You're  
25 correct.

1 JAMES W. BUCKLEY, JR.

2 Q. Your understanding is that that's a term of  
3 the settlement, correct?

4 A. Yes.

5 Q. So if that settlement is approved by the  
6 court and implemented and AWP is rolled back by First  
7 DataBank, don't you expect that under the master  
8 agreement pursuant to which Medco is currently  
9 providing services to your fund that the pricing is  
10 going to be revised to reduce the discounts to  
11 reflect the lower AWPs?

12 MR. NOTARGIACOMO: Objection. Calls for  
13 speculation

14 You can answer.

15 THE WITNESS: I would assume that Medco  
16 will be coming up with a new AWP. And if there's a  
17 new AWP, which would be reduced by the -- in the  
18 article in the paper, that there would be savings to  
19 the fund, yes

20 BY MR. FLUM:

21 Q. Well, if -- your understanding is that if  
22 the settlement's approved, First DataBank's published  
23 AWPs are going to be reduced to -- from a markup of  
24 25 percent over WAC to 20 percent, correct?

25 A. Correct

1 JAMES W. BUCKLEY, JR.

2 Q. So that means, does it not, that the  
3 nominal price -- I'm sorry -- the benchmark, the  
4 published benchmark for prescription drugs is going  
5 to go down?

6 A. Yes

7 Q. Now, do you have any understanding as to  
8 how Medco's contracts with retailers is structured?

9 A. No. We weren't involved in that at all.

10 Q. Is it your expectation that Medco  
11 negotiates hard to get as good a deal as it can from  
12 retailers?

13 MR. NOTARGIACOMO: Objection.

14 THE WITNESS: That's a fair assumption.

15 BY MR. FLUM

16 Q. So is it your expectation that Medco is  
17 hanging the smallest amount that it can negotiate  
18 above the retailers' acquisition cost for  
19 prescription drugs?

20 MR. NOTARGIACOMO: Objection.

21 THE WITNESS: It's a fair assumption.

22 BY MR. FLUM

23 Q. And if the published AWP's are reduced  
24 pursuant to the settlement, don't you expect that the  
25 retailers are going to insist that Medco renegotiate

1 JAMES W. BUCKLEY, JR.

2 its agreements with them?

3 MR. NOTARGIACOMO: Objection.

4 THE WITNESS: I can't -- I don't know what  
5 Medco and the retailers are going to do.

6 BY MR. FLUM:

7 Q. Well, you don't expect that the retailers  
8 are going to sell below their cost, do you?

9 MR. NOTARGIACOMO: Objection.

10 THE WITNESS: I can't answer for them.

11 BY MR. FLUM:

12 Q. Well, I'm not asking you to answer for  
13 them. But you certainly don't expect that the  
14 retailers are going to be selling drugs to Medco  
15 below their cost, correct?

16 MR. NOTARGIACOMO: Objection.

17 THE WITNESS: Well, if -- if they were  
18 getting 25 percent above what they were supposed to  
19 be getting for this -- for a specific time frame,  
20 they were -- they got more money than they were  
21 supposed to. So if it gets reduced, they have to  
22 figure that out with Medco.

23 BY MR. FLUM

24 Q. Let's turn to -- Let me find it -- page 11  
25 of Exhibit 11 Do you see there's a Heading No. 6,

1 JAMES W. BUCKLEY, JR.

2 "Formulary"? Do you see that?

3 A. Yes, I do.

4 Q. And do you see under that heading it says  
5 that "Each trust will have the option of either (1)  
6 being a participating plan sponsor in Medco's  
7 preferred prescription formulary, or (2) using its  
8 own current customized formulary."

9 Which option is the New England  
10 Carpenters Fund using?

11 A. Off the top of my head, I can't tell you,  
12 other than that this -- all this data was presented  
13 to Martin E. Segal, and Segal reviewed it with PSG  
14 and came back with a recommendation to the board on  
15 which way we should go. And at this time I don't  
16 remember which option we did take

17 Q. So let's turn to page 22 of the master  
18 agreement. This is Schedule A, "Program Pricing  
19 Terms" --

20 A. Yes.

21 Q. -- do you see that?

22 A. Yes, I do.

23 Q. And under "Retail pharmacy program claims  
24 (broad network)," there's a paragraph 1.1 for  
25 "Covered drugs," and it includes three different



1 JAMES W. BUCKLEY, JR.

2 pricing options. One of them is: AWP minus  
3 16 percent, plus the dispensing fee."

4 Do you see that?

5 A. Yes, I do.

6 Q. And then under Heading 2 of that same  
7 section is -- which is "Retail pharmacy program  
8 claims (select network)," there are again three  
9 options for pricing for covered drugs. One of them  
10 is "AWP minus 17 percent, plus the dispensing fee."

11 Do you see that?

12 A. I see that also.

13 Q. So which one of those networks is the fund  
14 using?

15 A. Currently right now I don't recall.

16 Q. Do you remember what the --

17 A. And I --

18 Q. -- discount off AWP is that the fund is  
19 currently receiving?

20 A. The answer is I don't -- I don't recall at  
21 this point. But I will give you the same answer that  
22 I gave you in the previous one that you asked me:  
23 that this information would have been reviewed by  
24 Segal and brought to the board and the board would  
25 have voted on it based on Segal's recommendation.

1 JAMES W. BUCKLEY, JR.

2 Q Are there documents that reflect the  
3 board's selection of --

4 A There should be information in the minutes.

5 Q I'm going to go back and finish my  
6 question. My question is, are there documents that  
7 reflect the board's -- I'm sorry. Are there  
8 documents that reflect the fund's selection of a  
9 pharmacy network under the master agreement?

10 A There -- It would be within the minutes.

11 Q And same question with respect to selection  
12 of a formulary?

13 A Correct. Same -- my same --

14 Q Same answer?

15 A Same answer.

16 Q In the minutes?

17 A Yes.

18 Q And you're not aware of any other documents  
19 that would reflect the choice of the network or the  
20 formulary?

21 A No.

22 Q Now, there is another document that your  
23 counsel gave me this morning. It's a trust  
24 participation agreement. And it appears to be  
25 between the -- well, it's actually between Medco and

1 JAMES W. BUCKLEY, JR.

2 the New England Carpenters Fund.

3 Are you familiar with that agreement?

4 A. I'd have to -- I'd like to see it.

5 Q. I'm happy to show it to you.

6 A. Okay.

7 MR. FLUM Is that 12?

8 THE COURT REPORTER: Yes.

9 (N.E. Carpenters Exhibit No. 12  
10 was marked for identification.)

11 BY MR. FLUM:

12 Q. So the court reporter has just handed you  
13 what we've marked as Exhibit 12 to this deposition.  
14 This is a document entitled "Trust Participation  
15 Agreement." I just received it from your counsel  
16 this morning.

17 Have you seen this before?

18 A. Yes. Except that it was addressed to  
19 Harry I don't think it came directly to me, but I  
20 did receive a copy of this.

21 Q. What do you understand the purpose of this  
22 agreement to be?

23 A. This was -- this was -- this is probably  
24 the This probably answers your questions that you  
25 had asked me because this would have been what would

1 JAMES W. BUCKLEY, JR.

2 have been executed at a board meeting through Segal's  
3 advice to the fund in reference to, I believe, these  
4 questions that you previously asked me.

5 Q. So it's your belief that this trust  
6 participation agreement is the document that governs  
7 the relationship between the New England Carpenters  
8 Trust and Medco currently?

9 A. Or -- or through the international through  
10 Medco, yes. It's also mentioning in here, pursuant  
11 to the prescription drug program master agreement  
12 with the United Brotherhood of Carpenters.

13 Q. Absolutely. And that's the agreement we  
14 were just looking at, marked as Exhibit 11 --

15 A. Correct.

16 Q. -- to your understanding?

17 A. Correct.

18 Q. And you see in that same paragraph you're  
19 looking at, if you read down a little further, four  
20 lines up from the bottom of the paragraph, it says,  
21 "The master agreement is hereby incorporated by  
22 reference and made a part of this trust participation  
23 agreement, as applicable"?

24 A. Correct.

25 Q. I'll just point out to you that if you turn

1 JAMES W. BUCKLEY, JR.

2 to page 5 of the agreement -- this is the trust  
3 participation agreement that we marked as  
4 Exhibit 12 -- there's a Schedule A, "Program Pricing  
5 Terms." And this contains Section 1, "Retail  
6 pharmacy program claims (broad network)" with the AWP  
7 minus 16 percent discount and Section 2, entitled  
8 "Retail pharmacy program claims (select network)"  
9 with the AWP minus 17 percent discount. But the  
10 agreement doesn't specify what your plan has  
11 selected.

12 So other than the board minutes you  
13 previously talked about, are you aware of any  
14 agreements that would reflect the fund's choice --

15 A No.

16 Q -- of the networks?

17 A. The answer is no.

18 MR. NOTARGIACOMO: And just for the sake of  
19 being complete --

20 MR. FLUM: Yes.

21 MR. NOTARGIACOMO if you turn to  
22 page 21

23 MR. FLUM: Is the answer there?

24 MR. NOTARGIACOMO I believe the  
25 answer's there

1 JAMES W. BUCKLEY, JR.

2 MR. FLUM: That's terrific. Thank you.  
3 Having just gotten these this morning, I didn't have  
4 a chance to study them carefully, so I appreciate the  
5 help.

6 MR. NOTARGIACOMO: I believe. I mean, I'm  
7 just looking at them myself. I think.

8 BY MR. FLUM:

9 Q. So your counsel is referring to some --  
10 a chart that appears on page 21 of Exhibit 12.  
11 Mr. Buckley, do you have any understanding as to what  
12 that chart reflects?

13 A. It's asking -- It's selecting the  
14 participating retail network. It's also rebate  
15 network. It's also dealing with formulary. So yes.  
16 On the previous page it talks about performance  
17 standards and implementation guarantees

18 Q You can put that aside.

19 Now, the fund went through a process  
20 in 2001 to request responses to a request for  
21 proposal for a new PBM, correct?

22 A RFPs were sent out, yes.

23 And Segal ran that process for you,  
24 correct?

25 A. That's correct. They always do, yes.

1 JAMES W. BUCKLEY, JR.

2 Exhibit 16 in response to that request?

3 A. Yes.

4 Q. And if you turn to the second page, do you  
5 see there's a heading "three-tiered co-payments"?

6 A. Yes.

7 Q. And then there are references there to  
8 "The fund may want to consider the possibility of  
9 adding a three-tier co-payment to replace the  
10 existing \$5 generic retail/\$10 brand retail."  
11 And then there's a chart that's got some additional  
12 co-payments listed.

13 Do you see that?

14 A. Yes.

15 Q. So does this refresh your recollection that  
16 the plan went to the three-tier co-payment sometime  
17 after September 2002?

18 A. Yes.

19 Q. And in fact, when you went to the three-  
20 tier co-payment - Well, actually let me ask you  
21 this. Was there initially a \$16 co-payment for  
22 nonpreferred, or did the plan go directly to 20?

23 A. We never had a 16.

24 Q. So when the plan went to the three-tier  
25 co payment, it went farther than Segal was

1 JAMES W. BUCKLEY, JR.

2 illustrating in this chart, correct?

3 A. No. The last Option II is on the chart.  
4 Segal has no --

5 Q. Oh, I see. I see. So what the plan  
6 adopted, ultimately Option II, that's shown in the  
7 memo we've marked as Exhibit 16, correct?

8 A. Yes.

9 Q. And that, in fact, is the option with the  
10 highest co-pays, correct?

11 A. Yes.

12 Q. Now, the effect of adopting those higher  
13 co-pays was that your members and their eligible  
14 dependents who were purchasing drugs within the  
15 higher tiers were bearing a larger number of the  
16 dollars that were being paid for prescriptions --

17 A. Yes.

18 Q. -- was it not?

19 A. Yes

20 Q. Now, these co-pay options that are set out  
21 in the Segal memo are tied to a formulary; are they  
22 not?

23 A. Yes.

24 Q. Is there a listing -- Let me back up.  
25 Let me try it this way



1 JAMES W. BUCKLEY, JR.

2 C E R T I F I C A T E

3  
4 I, Kimberly A Smith, a Certified Realtime  
5 Reporter, Registered Diplomate Reporter, and Notary  
6 Public in and for the Commonwealth of Massachusetts,  
7 do hereby certify that the foregoing is a true and  
8 accurate transcript of my stenographic notes of the  
9 deposition of JAMES W. BUCKLEY, JR., who was first  
10 duly sworn, taken at the place and on the date  
11 hereinbefore set forth.

12 I further certify that I am neither attorney or  
13 counsel for, nor related to or employed by any of the  
14 parties to the action in which this deposition was  
15 taken, and further that I am not a relative or  
16 employee of any attorney or counsel employed in this  
17 case, nor am I financially interested in this action

18 THE FOREGOING CERTIFICATION OF THIS TRANSCRIPT  
19 DOES NOT APPLY TO ANY REPRODUCTION OF THE SAME BY ANY  
20 MEANS UNLESS UNDER THE DIRECT CONTROL AND/OR  
21 DIRECTION OF THE CERTIFYING COURT REPORTER

22 This deposition was taken on the 15th day of October, 2006

23  
24  
25 KIMBERLY A. SMITH, CRR, RDR

JAMES W. BUCKLEY, JR.  
UNITED STATES DISTRICT COURT  
DISTRICT OF MASSACHUSETTS

 **COPY**

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NEW ENGLAND CARPENTERS HEALTH  
BENEFITS FUND, et al.,  
Plaintiffs,

v.

Civil Action

FIRST DATABANK, INC., and  
McKESSON CORPORATION,  
Defendants.

No. 1:05-CV-11148-PBS

----- X

VOLUME II

Pages 202-274

VIDEOTAPED DEPOSITION OF JAMES W BUCKLEY, JR.,  
a witness called by counsel for the Defendant,  
McKesson Corporation, taken before Kimberly A. Smith,  
Certified Realtime Reporter, Registered Diplomate  
Reporter, and Notary Public in and for the  
Commonwealth of Massachusetts, at the Law Offices of  
Bonner, Kiernan, Trebach & Crociata, LLP, One Liberty  
Square, Boston, Massachusetts 02109, on Tuesday,  
November 7, 2006, commencing at 10:59 a.m.

1 JAMES W. BUCKLEY, JR.

2 A. I don't recall seeing it.

3 Q. Do you recall that in May 2003, Segal was  
4 recommending that the fund change the network that it  
5 was using through AdvancePCS in order to save money?

6 A. I do recall that sometime -- and I don't  
7 remember whether it was 2003 -- I do recall that --  
8 Segal coming to the board and mentioning that PCS did  
9 have a different -- different type of network, and it  
10 would be advantageous to the fund to look into it.

11 Q. And it would be advantageous in the sense  
12 that using that other network would save the fund  
13 money, right?

14 A. Based on this document, the answer is yes.

15 Q. And can you tell me whether the fund --  
16 Well, actually I'll withdraw that.

17 Did AdvancePCS offer this alternative  
18 network to the fund in response to a request that the  
19 fund made?

20 A. I don't know. I don't know the answer to  
21 that.

22 Q. Do you know how it is that AdvancePCS came  
23 to be offering this alternative network with better  
24 pricing to the fund in May of 2003?

25 A. Not that I'm aware of.

1 JAMES W. BUCKLEY, JR.

2 C E R T I F I C A T E

3  
4 I, Kimberly A. Smith, a Certified Realtime  
5 Reporter, Registered Diplomat Reporter, and Notary  
6 Public in and for the Commonwealth of Massachusetts,  
7 do hereby certify that the foregoing is a true and  
8 accurate transcript of my stenographic notes of the  
9 deposition of JAMES W. BUCKLEY, JR., who was first  
10 duly sworn, taken at the place and on the date  
11 hereinbefore set forth.

12 I further certify that I am neither attorney or  
13 counsel for, nor related to or employed by any of the  
14 parties to the action in which this deposition was  
15 taken, and further that I am not a relative or  
16 employee of any attorney or counsel employed in this  
17 case, nor am I financially interested in this action.

18 THE FOREGOING CERTIFICATION OF THIS TRANSCRIPT  
19 DOES NOT APPLY TO ANY REPRODUCTION OF THE SAME BY ANY  
20 MEANS UNLESS UNDER THE DIRECT CONTROL AND/OR  
21 DIRECTION OF THE CERTIFYING COURT REPORTER.

22 Signed and sealed this 10th day of November, 2006.

23  
24  
25 KIMBERLY A. SMITH, CRR, RDR

# **Exhibit 16B**

**ADVANCEPCS HEALTH, L.P.****MANAGED PHARMACEUTICAL BENEFIT AGREEMENT**

THIS AGREEMENT (the "Agreement") is made as of April 1, 2001 (the "Effective Date") by and between MASSACHUSETTS STATE CARPENTERS ("Customer") and AdvancePCS Health, L.P., a Delaware limited partnership, as an indirect wholly owned subsidiary of AdvancePCS, a Delaware corporation, together with its affiliates ("AdvancePCS"), for the purpose of delineating the terms and conditions under which AdvancePCS will provide certain managed pharmaceutical benefit services to Customer. All capitalized terms will have the meanings given in this Agreement or in Section 11 of this Agreement.

**A G R E E M E N T****1. STATEMENT OF SERVICES/ADVANCEPCS OBLIGATIONS**

- 1.1. **Services.** AdvancePCS will provide Customer the services, including the Base Services (those Services described in Exhibit A—Sections 1, 3, 4 (other than 4B and 4E), 5, 6, 9, 10 (other than 10B), 11A, 12 and 13E) and such other services listed in Exhibit A hereto which are selected by Customer pursuant to the implementation documents (collectively the "Services"). AdvancePCS may change the Services upon 30 days' prior written notice to Customer, subject to Customer's right to terminate under Section 8.2.2 of this Agreement. Services will not be discontinued or materially reduced except upon the mutual agreement of the parties. Customer acknowledges that AdvancePCS may upgrade and make minor modifications to the Services without notice to Customer.
- 1.2. **Compliance with Law.** AdvancePCS will comply with all Laws applicable to it and the Services it provides under this Agreement. Customer has no responsibility to advise AdvancePCS regarding its compliance with any applicable Law. AdvancePCS makes no representation or warranty that the Plan Design selected by Customer is in compliance with any Law that applies to Customer.
- 1.3. **AdvancePCS Indemnity.** Subject to the limitations set forth in Section 6.4 of this Agreement, AdvancePCS will indemnify and hold harmless Customer for, from and against any and all costs, losses or damages Customer may incur as a result of AdvancePCS' failure to perform any of its obligations under this Agreement.
- 1.4. **Performance Standards.** AdvancePCS shall provide Services consistent with the performance standards listed in Exhibit C. If AdvancePCS fails to perform in accordance with the standards listed in Exhibit C, Customer shall give written notification to AdvancePCS.

**2. FEES AND PAYMENT**

- 2.1. **Fees.** Customer will pay to AdvancePCS the Administrative Fees listed in Exhibit B, as applicable. AdvancePCS will invoice Customer for such Administrative Fees monthly, and payment is due within 10 days of Customer's receipt of the invoice.

**2.2. Rates for Prescription Claims.** Customer will pay for Covered Items dispensed to Members by the mail service pharmacy or the Network Providers, as the case may be, at the rates set forth in Exhibit B attached hereto, unless otherwise previously or hereafter hardcoded for different pricing at Customer's request.

**2.2.1.** AdvancePCS has established a payment cycle for payments to Network Providers or Members for Covered Items, and following each cycle, AdvancePCS will invoice Customer for the amount due based on Claims submitted. AdvancePCS may change this payment cycle during the term of this Agreement, to a period determined by AdvancePCS in its sole discretion, upon 10 days' prior written notice to Customer.

**2.2.2.** Within two (2) days of receipt of such invoice, Customer will wire transfer the invoiced amount to such account as AdvancePCS may designate from time to time.

**2.2.3.** The amount that Customer pays to AdvancePCS under this Section 2.2 is not an asset of Customer's prescription benefit plan. AdvancePCS has no obligation to Customer or Customer's prescription benefit plan with respect to the interest or other earnings, if any, received by AdvancePCS with respect to these amounts.

**2.2.4.** When Customer has made payment to AdvancePCS in full as described in this Section 2.2: (i) AdvancePCS will release Customer from any responsibility for the payment of any amounts owing to Network Providers or Members; and (ii) AdvancePCS will indemnify, defend and hold harmless Customer for, from and against any claims or demands from Network Providers or Members arising out of AdvancePCS' failure to remit amounts to Network Providers or Members as payment for Covered Items dispensed.

**2.3. Certain Remedies.** Notwithstanding Section 9 of this Agreement, if Customer fails to pay AdvancePCS by the due date any amount owing hereunder, AdvancePCS, after making a good faith effort to collect and upon immediate written notice to Customer via facsimile to the facsimile number provided in this Agreement, may do any or all of the following:

**2.3.1.** Suspend performance of any and all of AdvancePCS' obligations under or in connection with this Agreement, including AdvancePCS' obligation to process Claims using the RECAP System;

**2.3.2.** Immediately advise Network Providers that the RECAP System is not available in connection with the Plan Design;

**2.3.3.** Apply all or any portion of any security posted by Customer with AdvancePCS to Customer's delinquent account; or

**2.3.4.** Set off against any amounts otherwise payable to Customer under this Agreement (including, if AdvancePCS is providing Formulary Services to Customer, any Rebates AdvancePCS receives from a Manufacturer on behalf of Customer) any amounts due from Customer under this Agreement.

**2.4. Security.** If at any time during the term of this Agreement AdvancePCS reasonably determines, based on Claims volume, payment record or Customer's latest financial information, that Customer may have difficulty meeting its financial commitments under this Agreement, AdvancePCS may require Customer to provide security in an amount and form that AdvancePCS deems necessary provided that the amount is reasonable in relationship to the Claims volume. Customer will provide such security within 10 days of AdvancePCS' request. Additionally, Customer will furnish audited financial statements to AdvancePCS upon AdvancePCS' request. AdvancePCS will keep these audited financial statements confidential and will use them solely for internal review purposes to determine credit requirements.

**2.5. Pricing Changes.**

**2.5.1.** After the Initial Term of this Agreement, AdvancePCS may change the Administrative Fees applicable to the Plan Design after giving Customer 60 days' written notice. Any change will take effect on the first day of the month following the 60 day notice period. Customer may object to an increase in Administrative Fees by providing written notice to AdvancePCS at least 30 days before the expiration of the 60 day notice period. If the parties cannot agree on an appropriate Administrative Fee, the Agreement will terminate at the end of the 60 day notice period. If Customer does not timely object, Customer will have no right to terminate this Agreement based on the pricing change.

**2.5.2.** The rates provided to Customer in this Agreement are subject to certain Plan Design requirements. If there occurs a material change in drug industry practice which materially alters the rights and obligations of AdvancePCS under this Agreement, the parties will attempt to equitably adjust the pricing under this Agreement. If the parties are unable to agree upon an equitable adjustment, this Agreement will terminate on 60 days after notice by either party of such termination.

**3. CUSTOMER OBLIGATIONS**

**3.1. Plan Design Information; Member Eligibility.** Throughout the term of this Agreement, Customer, at its expense, will provide AdvancePCS all information concerning Customer's Plan Design and Members needed to perform the Services, including, without limitation, processing parameters and Member enrollment and eligibility updates. This information must be complete and accurate, provided timely and in a format and media approved by AdvancePCS. (Member enrollment and eligibility information is collectively referred to as "Eligibility Information").

**3.2. Reports.** AdvancePCS may provide Customer with reports showing (i) all or some portion of the Plan Design information submitted to AdvancePCS, (ii) Member enrollment or eligibility data, (iii) Claims or billing activity during a specific period, or (iv) any action(s) taken by AdvancePCS in performing Services. Customer will review all such reports and notify AdvancePCS in writing of any errors or objections within 45 days of receipt of the report. Until Customer notifies AdvancePCS of any errors or objections, AdvancePCS will be entitled to rely on the information contained in the report. If Customer does not notify AdvancePCS of any errors or objections within the



45 day period, the information contained in the report will be deemed accurate, complete and acceptable to Customer.

- 3.3. **Drug Classification.** Customer agrees to accept the latest edition of the First DataBank Blue Book (with supplements) or any other similar nationally recognized reference that AdvancePCS may select from time to time as the source for purposes of classifying drugs (e.g., legend vs. over the counter, brand vs. generic) in connection with this Agreement.
- 3.4. **Member Authorizations.** Customer has obtained, or will obtain, all Member authorizations required by Law, for AdvancePCS to perform the Services (including, without limitation, AdvancePCS audits of Network Providers and the Services required by Exhibit A Sections 5(B), 5(C), 6 and 11(C)).
- 3.5. **Customer Indemnity.** Subject to the limitations of Section 6.4 of this Agreement, Customer will indemnify and hold harmless AdvancePCS for, from and against any and all costs, losses or damages that AdvancePCS may incur as a result of Customer's failure to perform any of its obligations under this Agreement.
- 3.6. **Compliance with Law.** Customer will comply with all Laws applicable to its prescription drug benefit plan. AdvancePCS has no responsibility to advise Customer about Customer's compliance with any applicable Law including, without limitation, the Employee Retirement Income Security Act ("ERISA") or the Americans with Disabilities Act ("ADA"). Customer will also disclose to Members any and all matters relating to the Plan Design that are required by Law to be disclosed, including information relating to the calculation of copayments, coinsurance amounts, deductibles or any other amounts that are payable by a Member in connection with the Plan Design; and Rebates or other discounts on pharmaceutical products if Customer has selected Formulary Services, irrespective of whether Customer retains or allows AdvancePCS or others to retain all or a portion of any Rebates or discounts.

#### 4. USE AND ACCESS TO INFORMATION

- 4.1. **Use of Information.** Subject to Section 5 of this Agreement, AdvancePCS and Customer may use the information obtained in connection with Claims ("Claims Information"), as well as Eligibility Information, in any manner they deem appropriate; except that each party and its agents, employees and contractors must maintain the confidentiality of this information (including the identity of any Member or Customer) to the extent required by applicable Law, and may not use this information in any manner prohibited by Law. Each party is responsible for its own use of the Claims Information and Eligibility Information, and will indemnify and hold harmless the other party for, from and against any and all costs, losses and damages incurred as a result of such use, including any claim by an employee or former employee of Customer or any of its affiliates under Law that protects the rights of such employees or their beneficiaries, including, without limitation, ERISA and the ADA.
- 4.2. **Access to Records.** AdvancePCS will maintain records of the Claims Information for 7 years after the dispensing date. These records will be in a format and media deemed appropriate by AdvancePCS. Customer may audit, review and duplicate the Claim billing information used by AdvancePCS to invoice Customer under this Agreement.

AdvancePCS may audit, review and duplicate the Claims Information, and any other records Customer may have regarding the Claims Information made in connection with this Agreement. Reasonable prior written notice must be provided before an audit to the party holding the applicable information or records. All audits will be at the auditing party's expense, must occur during regular business hours at the place of business of the holder of the information, are subject to all Laws regarding confidentiality, and are subject to the provisions of Section 5 of this Agreement. The party requesting duplication will pay the other party its reasonable duplicating costs.

**4.3. Third Party Records Request.**

**4.3.1.** If a Member or a Member's agent or designee requests to review or duplicate any Records, AdvancePCS will refer the requestor to Customer, and Customer may then request the Records in accordance with Section 4.2 of this Agreement.

**4.3.2.** If either party receives a court order, subpoena or governmental request for Records, the party will use its best efforts to timely notify the other party of the receipt of such request and provide an opportunity to respond. The receiving party may comply with such order, subpoena or request. If such order, subpoena or request relates directly to the other party's business (or in the case of Customer to a Member's Records) and not to the complying party's business generally, the complying party is entitled to reimbursement from the other party for its reasonable compliance costs.

**4.4. Product Development.** Subject to Section 4.1 of this Agreement, AdvancePCS, its agents, employees and contractors may use, reproduce, or adapt any information obtained under this Agreement or any prior agreement with Customer, to render services to clients and to develop new products and services which may be outside the scope of this Agreement. Any work, compilation, processes, or inventions developed by AdvancePCS or its agents, employees or contractors under this Section 4.4 is deemed AdvancePCS' Confidential Information under Section 5.1 of this Agreement.

**5. INTELLECTUAL PROPERTY**

**5.1. Proprietary Information.** In connection with this Agreement, each party may disclose to the other party certain proprietary or confidential technical and business information, databases, trade secrets, and innovations belonging to the disclosing party ("**Confidential Information**"), the value of which might be lost if the proprietary nature or confidentiality of such Confidential Information is not maintained. Each party agrees to the following provisions:

**5.1.1.** For the purposes of this Section 5, this Agreement and any exhibits, amendments or addenda attached hereto are deemed Confidential Information.

**5.1.2.** Each party reserves all rights to its Confidential Information, including all proprietary and novel features. Neither party will disclose any of the other party's Confidential Information nor use any of the other party's Confidential Information to benefit itself or others except to the extent expressly authorized in this Agreement.

5.1.3. Each party will treat all Confidential Information as confidential; will disclose Confidential Information only to its employees who have a need to know in order to accomplish the purpose permitted in this Agreement and who themselves agree not to disclose it to anyone; will not (except to the extent expressly authorized by this Agreement) disclose Confidential Information to anyone outside of AdvancePCS or Customer; and will not copy or reproduce any written materials or tangible items provided by the other party unless expressly authorized to do so in writing. AdvancePCS and Customer each will take at least all measures it employs with respect to information of its own that it regards as confidential and proprietary, to preserve and protect the confidentiality or proprietary nature of any Confidential Information and to prevent it from falling into the public domain or into the possession of persons not bound to maintain its confidentiality.

5.1.4. All Confidential Information will remain the property of the disclosing party. The receiving party will return all written or tangible materials, and all copies thereof, upon request of the disclosing party.

5.1.5. The receiving party will not be liable for any disclosure or use of any Confidential Information if the Confidential Information is publicly available or later becomes publicly available other than through a breach of this Agreement, or if the Confidential Information is shown by written documentation to be known to the receiving party on the date of execution of this Agreement. Confidential Information may be disclosed pursuant to a bona fide subpoena if the party receiving the bona fide subpoena has given the other party immediate written notice of receipt of the subpoena so that the other party can objection or otherwise intervene as it deems proper.

5.2. **RECAP.** AdvancePCS owns the compilations of information contained in: (i) AdvancePCS' RECAP System, including, but not limited to, all printouts and copies, as well as any prior or future versions by any name; (ii) all other databases developed by AdvancePCS or its designees in connection with performing drug benefit services or utilization review; or (iii) the Services. In addition, these compilations are protected by copyright owned by AdvancePCS.

5.3. **Remedies.** Any unauthorized disclosure or use of Confidential Information would cause AdvancePCS or Customer immediate and irreparable injury or loss. Accordingly, if either party fails to comply with this Section 5, the other party will be entitled to specific performance including immediate issuance of a temporary restraining order or preliminary injunction enforcing this Agreement, and to judgment for damages (including reasonable attorneys' fees) caused by the breach, and to any other remedies provided by Law.

## 6. WARRANTY, LIMITATION OF LIABILITY

6.1. **Warranty.** This Agreement is not a contract for the sale of goods. AdvancePCS will perform the Services in a good and workmanlike manner in accordance with the customs, practices and standards of providers skilled in the industry. EXCEPT AS WARRANTED IN THIS SECTION 6.1, ADVANCEPCS DISCLAIMS ALL EXPRESS AND ALL IMPLIED WARRANTIES OF ANY KIND, INCLUDING THE

**SUITABILITY FOR ANY PARTICULAR PURPOSE OF THE DATA GENERATED THROUGH THE RECAP SYSTEM.**

- 6.2. Force Majeure.** Except for obligations set forth in Section 2 of this Agreement, the parties are excused from performance under this Agreement to the extent such party is prevented from performing any obligation, in whole or in part, as a result of causes beyond its reasonable control, including, acts of God, war, civil disturbance, court order, governmental intervention, Change in Law, nonperformance by the other party or any third party, failures or fluctuations in electrical power, heat, light, air conditioning or telecommunications equipment. Any nonperformance under this Section 6.2 will not constitute a default or a ground for termination of this Agreement.
- 6.3. Change in Law.** The parties will attempt to equitably adjust the terms of this Agreement to take into account any Change in Law that materially alters the rights or obligations of either party under this Agreement. If the parties are unable to agree upon an equitable adjustment within 60 days after either party notifies the other of a Change in Law, this Agreement will automatically terminate.
- 6.4. Limitations of Liability.**
- 6.4.1.** Neither Customer nor AdvancePCS (nor any of their affiliates, directors, employees, agents, successors or assigns) will be liable to the other under this Agreement:
- 6.4.1.1.** for any claim, demand, loss, attorneys' fees, costs, expenses, or liabilities of any kind arising from the acts or omissions of any pharmacy, pharmacist or provider that performs any Services in connection with this Agreement; or
- 6.4.1.2.** for any indirect, special, incidental or consequential damages, even if informed of their possibility.
- 6.4.2.** AdvancePCS (or any of its affiliates, directors, employees, agents, successors or assigns) will not be liable to Customer under this Agreement for any amount, arising out of one or more claims, except for actual or compensatory damages.
- 6.4.3.** Neither Customer nor AdvancePCS (nor any of their affiliates, directors, employees, agents, successors or assigns) will be liable for any claim which is asserted by the other party more than 180 days after the other party is or reasonably should have been aware of such claim. Providing the other party with written notice, setting forth in sufficient detail the bases for such claim, constitutes asserting the claim under this Section.
- 6.4.4.** If Customer has chosen not to receive those reports described in Section 3.2 or Exhibit A of this Agreement, AdvancePCS (or any of its affiliates, directors, employees, agents, successors or assigns) will not be liable for any claim which Customer reasonably would have been aware of if Customer had been receiving such reports.

7. **FORMULARY SERVICES.** If Customer selects Formulary Services, the provisions of this Section 7 will apply.

7.1. **Formulary Fees.** Customer will pay to AdvancePCS a fee in an amount equal to the percentage set forth in Exhibit B multiplied by the Rebates collected by AdvancePCS in connection with this Agreement. In lieu of billing Customer for these fees, AdvancePCS may retain the amount due from the Rebates collected by AdvancePCS on behalf of Customer.

7.2. **Formulary Limitations.** As used herein and in Exhibit A, "Manufacturer" means a pharmaceutical company that has contracted with AdvancePCS (or its affiliate or agent) to offer discounts for pharmaceutical products in connection with AdvancePCS' Formulary Services.

7.2.1. Customer and AdvancePCS waive, release, and forever discharge each other from any claims, demands, losses, attorneys' fees, costs, expenses and liabilities of any nature, whether known or unknown, arising from:

7.2.1.1. a Manufacturer's failure to pay any Rebate;

7.2.1.2. a Manufacturer's breach of an agreement related to this Agreement;  
or

7.2.1.3. a Manufacturer's negligence or misconduct.

7.2.2. AdvancePCS may receive fees or other compensation from Manufacturers, including, without limitation, administrative fees not exceeding 3% of the cost of the pharmaceutical products dispensed to Members, and fees for property provided or Services rendered to a Manufacturer (which may include providing physicians clinical messages consistent with the Performance Drug List). The term Rebates as used in this Agreement does not include these fees, which belong exclusively to AdvancePCS. In addition, AdvancePCS Mail, a mail service program provided by an affiliated mail service facility ("AdvancePCS Mail") may negotiate on its own behalf directly with Manufacturers for discounts, including rebated discounts based on market share or other factors. The term Rebates as used in the Agreement does not include these discounts which belong exclusively to AdvancePCS Mail.

7.3. **Formulary Ownership.** The AdvancePCS Formulary contains AdvancePCS proprietary information and AdvancePCS owns all rights to the AdvancePCS Formulary, including but not limited to, rights associated with publication, trade secrets, copyrights, trademarks and patents. Any rights that Customer may have in the AdvancePCS Formulary are hereby assigned to AdvancePCS. Accordingly, copies of the AdvancePCS Formulary in any medium distributed to Customer and its participating physicians remain the property of AdvancePCS and may be used only by Customer and such participating physicians for the purposes and transactions contemplated by this Agreement. Other than as expressly authorized in this Agreement, Customer may not distribute or disclose copies of the AdvancePCS Formulary to anyone, except as reasonably necessary for performance of this Agreement. Customer may not distribute or disclose copies of the AdvancePCS Formulary to any competitor of AdvancePCS.

- 7.4. **Formulary Renegotiation.** If, after the Effective Date of this Agreement, there occurs any Change in Law which materially affects AdvancePCS' ability to perform Formulary Services; or a change in drug industry practice which causes a substantial reduction in the Rebates available under this Agreement, either party may renegotiate the Formulary Services and Formulary Fees by providing written notice to the other party. For purposes of this Section 7.4, a "substantial reduction" of Rebates means that Rebates available for a particular year, after AdvancePCS attempts diligent collection of Rebates, are less than 80% of the actual Rebates paid or payable during the initial year of this Agreement. Termination of Formulary Services will not terminate this Agreement as a whole.

## 8. TERM AND TERMINATION OF AGREEMENT

- 8.1. **Term.** This Agreement is for an initial term of 3 years from the Effective Date (the "Initial Term"), and will automatically continue in effect for successive 3 year terms thereafter, subject to the remaining provisions of this Section 8.
- 8.2. **Termination.** This Agreement may be terminated as follows:
- 8.2.1. By either party, with or without cause, at the end of the Initial Term or any renewal term, by giving written notice to the other party 60 days prior to the end of such Initial Term or renewal term;
  - 8.2.2. By Customer, at its option, if AdvancePCS changes the Services under Section 1.1 of this Agreement, such termination to be effective on the proposed date the change would take effect;
  - 8.2.3. Automatically, if the parties are unable to agree on (i) changes in Administrative Fees under Section 2.5.1 of this Agreement, (ii) an equitable adjustment under Section 2.5.2 of this Agreement; or (iii) an equitable adjustment under Section 6.3 of this Agreement;
  - 8.2.4. By either party if the other party defaults in its performance of this Agreement. The terminating party must provide the defaulting party 30 days' prior written notice, specifying the nature of the default. This Agreement will not terminate under this subsection if the defaulting party cures the default within the 30 day period;
  - 8.2.5. By AdvancePCS (notwithstanding subsection 8.2.4 of this Agreement) on 2 days' prior written notice to Customer, if Customer fails (i) to timely make any payment required under this Agreement, unless Customer cures that default within the two-day period, or (ii) to provide or maintain security under Section 2.4 of this Agreement;
  - 8.2.6. By either party, at its option, if any court, governmental or regulatory agency issues to the other party an order or finding of impairment or insolvency, or an order to cease and desist from writing business. The party receiving notice of an order or finding must provide the other party written notice within 2 business days of receipt; or



8.2.7. By either party if the other party or Customer's guarantor: (i) makes an assignment for the benefit of creditors; (ii) has a petition filed (whether voluntary or involuntary) under Title 11 of the United States Code, or any other similar statute now or hereafter in effect; (iii) has a receiver, custodian, conservator or trustee appointed with respect to all or a substantial part of its property; or (iv) has a proceeding commenced against it which substantially impairs performance hereunder.

8.3. **Survival.** Sections 4, 5 and 6 of this Agreement, and obligations arising under this Agreement prior to the effective date of termination will survive termination.

8.4. **Pre-Termination Claims.** In the event this Agreement terminates for any reason, Customer, at its option, may elect to have AdvancePCS continue to provide Services for up to 12 months with respect to Claims incurred but not reported as of the effective date of termination. AdvancePCS' compensation for these Services will be in accordance with the terms in effect as of the effective date of termination.

## 9. NOTICES

All notices under this Agreement must be in writing, delivered in person, sent by certified mail, delivered by air courier, or transmitted by facsimile and confirmed in writing (by air courier or certified mail) to a party at the facsimile number and address shown in this Agreement. A party may notify the other party of any changes in the listed address or facsimile number in accordance with the provisions of this Section 9. The parties may also transmit notices electronically, when proper arrangements are made in advance to facilitate such communications and provide for their security and verification. All notices are effective upon receipt.

Notices to AdvancePCS must be addressed as follows:

Chief Executive Officer  
AdvancePCS  
5215 North O'Connor Boulevard, Suite 1600  
Irving, Texas 75039  
Fax No.: (469) 420-6109

And With A Copy To:

General Counsel  
AdvancePCS Health, L.P.  
9501 East Shea Boulevard  
Scottsdale, AZ 85260-6719  
Fax No.: (480) 314-8231

Notices to Customer must be addressed as follows:

Massachusetts State Carpenters  
350 Fordom Road  
Wilmington, MA 01887  
Attn: James W. Buckley, Jr.  
Fax No.: (617) 783-1836

## 10. MISCELLANEOUS

- 10.1. Interpretation; Amendment; Counterparts.** This Agreement (including exhibits, schedules, attachments, implementation documents, any addendum to this Agreement or such other documents AdvancePCS may require from time to time to implement Services, all collectively referred to as "Implementation Documents") constitutes the entire understanding and obligation of the parties with respect to the Services and supersedes any prior agreements, writings, or understandings, whether oral or written. The headings in this Agreement are used only for convenience of reference and do not affect the meaning or interpretation of any provision. The parties may amend this Agreement only through a properly executed writing authorized by both parties. This Agreement may be executed in several counterparts, all of which taken together constitute a single agreement between the parties.
- 10.2. Binding Effect; Assignment.** This Agreement is binding on the parties and their respective successors and permitted assigns. Neither party may assign this Agreement, in whole or in part, without the prior written consent of the other (which consent will not be unreasonably withheld); except that AdvancePCS may assign this Agreement, in whole or in part, to any entity that controls, is controlled by, or is under common control with AdvancePCS, provided it gives Customer 30 days written notice of the assignment.
- 10.3. Independent Contractor; Third Parties.** The parties to this Agreement are independent contractors, and have no other legal relationship under or in connection with this Agreement. No term or provision of this Agreement is for the benefit of any person who is not a party hereto (including, without limitation, any Member or broker), and no such party will have any right or cause of action hereunder.
- 10.4. Waivers.** Any failure by a party to comply with any covenant, agreement or condition herein or in any other agreements or instruments executed and delivered hereunder may be waived in writing by the party in whose favor such obligation or condition runs; except that failure to insist upon strict compliance with any such covenant, agreement or condition will not operate as a waiver of, or estoppel with respect to, any subsequent or other failure.
- 10.5. Severability.** In the event any term or provision of this Agreement is declared to be invalid or illegal for any reason, this Agreement will remain in full force and effect and will be interpreted as though such invalid or illegal provision were not a part of this Agreement. The remaining provisions will be construed to preserve the intent and purpose of this Agreement and the parties will negotiate in good faith to modify any invalidated provisions to preserve each party's anticipated benefits.
- 10.6. Enforcement Costs.** If either party institutes an action or proceeding to enforce any rights arising under this Agreement, the party prevailing in such action or proceeding will be paid all reasonable attorneys' fees and costs to enforce such rights by the other party, such fees and costs to be set by the court, not by a jury, and to be included in the judgment entered in such proceeding.
- 10.7. Authority.** Each party represents and warrants that it has the necessary power and authority to enter into this Agreement and to consummate the transactions contemplated by this Agreement.



- 10.8. **Governing Law.** This Agreement must be governed and construed in accordance with the laws of the Commonwealth of Massachusetts without regard to applicable conflicts of law rules.

## 11. DEFINITIONS

The following terms and phrases, when capitalized, have the meanings set forth below.

- 11.1. **"AdvancePCS"** shall mean the corporation AdvancePCS and any subsidiaries or affiliates thereof.
- 11.2. **"AWP"** means the average wholesale price of the drug dispensed as set forth in the latest edition of the First DataBank Blue Book (with supplements) or any other similar nationally recognized reference that AdvancePCS may select from time to time. The applicable AWP for Claims submitted by retail Network Providers is based on the average AWP for each drug.
- 11.3. **"Covered Items"** means the prescription drug benefits for which Members are eligible pursuant to Customer's drug benefit plan.
- 11.4. **"Change in Law"** means any (i) change in or adoption of any Law, (ii) change in the judicial or administrative interpretation of any Law, or (iii) change in the enforcement of any Law, occurring after the date Customer is implemented or the Effective Date, whichever is earlier.
- 11.5. **"Claims"** means those claims processed through the RECAP<sup>®</sup> System or otherwise transmitted or processed in accordance with the terms of this Agreement in connection with the Plan Design.
- 11.6. **"Law"** means any federal, state, local or other constitution, charter, act, statute, law, ordinance, code, rule, regulation, order, specified standards or objective criteria contained in any applicable permit or approval, or other legislative or administrative action of the United States of America, or any state or any agency, department, authority, political subdivision or other instrumentality thereof or a decree or judgment or order of a court.
- 11.7. **"Maximum Allowable Cost (MAC)."** AdvancePCS will use one or more of its proprietary maximum allowable cost pricing schedules ("MAC Lists") to establish an upper limit reimbursement price for certain multiple-source drugs dispensed under the Plan without regard to the specific manufacturer whose product is dispensed. The MAC Lists shall include generic drugs based on their common substitution, bioequivalency rating, and general availability. Customer agrees to accept any one of AdvancePCS' MAC Lists, as amended from time to time in AdvancePCS' discretion, for the purpose of pricing drugs in connection with this Agreement. Customer acknowledges that certain of AdvancePCS' national provider networks may utilize one or more of AdvancePCS' MAC Lists.
- 11.8. **"Member"** means an individual that Customer has designated in writing (or by electronic, tape or other means approved by AdvancePCS) to AdvancePCS as eligible for Covered Items under the terms of the Plan Design.

- 11.9. **"Network Provider"** means a provider which has agreed to provide certain pharmacy Services to Members in accordance with the terms of its agreement with AdvancePCS.
- 11.10. **"Plan Design"** means the processing parameters and other information concerning Customer's drug benefit plan, which Customer has disclosed to AdvancePCS pursuant to Section 3.1 of this Agreement, and which AdvancePCS will use to process Claims under this Agreement.
- 11.11. **"Rebate(s)"** means, for any period, all rebates, reimbursements, or other discounts received under a pharmaceutical manufacturer's discount program with respect to pharmaceutical products dispensed to a Member under the Plan Design for such period.
- 11.12. **"RECAP<sup>®</sup>"** or **"RECAP System"** means AdvancePCS' proprietary remote electronic claims adjudication process.

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IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed by their respective duly authorized officers or agents as of the date first above written.

MASSACHUSETTS STATE CARPENTERS

ADVANCEPCS HEALTH, L.P.

By: AdvancePCS Health Systems, LLC, its  
General Partner

By: Thomas Hanington

By: David A. George  
David A. George

Title: EST

Title: President

Date: 4-25-02

Date: 6-28-02

Legal MAA  
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## DESCRIPTION OF SERVICES

Below is a listing of Services provided under the base administrative fee or available for an additional fee. The Services are subject to change, at AdvancePCS' discretion, as provided in the Agreement. Capitalized terms not defined herein will have the meanings used in the Agreement.

### 1. PHARMACY MANAGEMENT

- A. **Network Providers.** AdvancePCS has created a network of pharmacies (Network Providers) that Members will have access to, which have agreed to perform pharmacy Services for Members in accordance with the Plan Design and the terms of the Network Provider Agreement. As provided for in the Network Provider Agreement, Network Providers may choose, in certain limited circumstances, not to perform pharmacy Services for Members under this Agreement; however, no Network Provider may serve only some Members or provide only certain drugs unless (i) such Network Provider does not provide such drugs to any Members, or (ii) such Network Provider deems the provisions of pharmacy Services to a given Member contrary to the Network Provider's professional judgment. AdvancePCS may provide Network Providers with Plan Design information in such format and media as AdvancePCS deems appropriate for the purpose of assisting such Network Providers in providing Covered Items to Members.
- B. **Retail Network Auditing.** AdvancePCS will perform the following audits of retail Network Providers on behalf of Customer. Customer will not have the right to independently audit Network Providers.
- **Statistical Auditing.** AdvancePCS will perform a periodic computerized analysis of those retail Network Providers handling a significant number of Claims which compares their Claims activity to the Claims activity of similar pharmacies. From this analysis, AdvancePCS will select pharmacies for, among other things, field audits.
  - **Field Auditing.** Each year during the term of the Agreement, AdvancePCS will perform field audits of retail Network Providers selected by AdvancePCS, to examine a retail Network Provider's compliance with its retail Network Provider Agreement. Any additional audit by AdvancePCS of any pharmacies selected by Customer will be additional services subject to additional charges.
  - **Audit Discrepancies.** To the extent AdvancePCS determines, as the result of its auditing procedures, that amounts have been overpaid to pharmacies for Claims submitted ("**Audit Discrepancies**"), AdvancePCS will make reasonable attempts to collect such Audit Discrepancies and any Audit Discrepancies so collected will be returned to Customer; provided, however, that AdvancePCS will retain 10% of such collected Audit Discrepancies to cover AdvancePCS' collection costs. AdvancePCS will notify Customer of any audit discrepancy that is greater than \$1,000 after AdvancePCS determines such audit discrepancy to be reasonably uncollectible by AdvancePCS. AdvancePCS will not be required to institute litigation to collect any Audit Discrepancies. AdvancePCS' obligation to attempt collection will be AdvancePCS' sole obligation and liability with respect to remedying such Audit Discrepancies.

*DESCRIPTION OF SERVICES*

- C. **Pharmacy Help Desk and Voice Response Unit.** AdvancePCS will provide assistance to Network Providers through the RECAP Pharmacy Help Desk and AdvancePCS' voice response unit during those hours of operation established by AdvancePCS.

2. **MEMBER SERVICE/TOLL FREE MEMBER SERVICES**

AdvancePCS will make available to Members a toll free number during those hours of operation established by AdvancePCS from time to time. Staff will be available to answer Members' questions on Plan Design eligibility, Plan Design guidelines, deductible status and required copay levels, maximum benefit status, status of an identification card order, instructions for completing a Direct Claim (as defined in Section 4B below) form and status of Direct Claims.

3. **ELIGIBILITY SERVICES**

- A. **Identification Cards.** AdvancePCS will design one identification card layout and provide Customer with a proof of final design layout. Customer will provide AdvancePCS with camera-ready artwork for the logo or logos that Customer wants to appear on the identification card. All identification cards will include the AdvancePCS or RECAP name and logo. For each Member, AdvancePCS will generate standard AdvancePCS cards in such final design.
- B. **Eligibility File.** Based upon the information provided by Customer to AdvancePCS pursuant to Section 3.1, AdvancePCS will maintain an eligibility file identifying current Members and certain other information regarding such Members.

4. **CLAIMS PROCESSING**

- A. **Provider Submitted Point of Sale ("POS") Claims.** AdvancePCS will accept Claims submitted by Network Providers to AdvancePCS via the RECAP System (or as otherwise permitted under the Network Provider Agreement) and process such Claims in accordance with this Section 4A as follows:

- AdvancePCS will enter into the RECAP System those portions of the Plan Design information as are necessary for AdvancePCS to perform automated Claims processing Services in accordance with this Agreement, including information regarding deductibles, copays, Member or Customer out-of-pocket maximums, benefit maximums and other features of the Plan Design to be used in processing Claims (collectively, "Processing Parameters").
- AdvancePCS will instruct Network Providers to transmit certain prescription, eligibility, and Plan Design information to AdvancePCS when the Member presents a Plan identification card, and if the RECAP System is unavailable, as soon as possible after the system becomes available. If the RECAP System is unavailable, the Network Providers may submit the prescription at a later time and/or call the AdvancePCS RECAP Help Desk to verify eligibility.
- AdvancePCS will perform RECAP System edits and transmit to such Network Provider the Claim status, the copay/coinsurance/deductible amount (if applicable), and any applicable DUR (as defined in Section 5A below) or other messages.

*EXHIBIT A*  
*DESCRIPTION OF SERVICES*

- Customer acknowledges that Network Providers will collect from the Member at the point of sale the lesser of the applicable copay/coinsurance/deductible amount or the usual and customary price of that pharmacy.
  - Certain drugs that become available on the market from time to time will be priced separately from, and thus not subject to the contracted rate for prescription Claims due to, among other things, specialized manufacturer processes, limited availability or extraordinary shipping requirements. Such drugs presently include biotechnology drugs, such as Betaseron and Avonex, compounds, and injectables. AdvancePCS will provide Customer with a list of such drugs, and their corresponding rates (which are generally no less than full AWP), upon request. Network Providers, subject to the exceptions previously set forth in Section 1-A of this Exhibit A, Description of Services, will dispense these drugs to Members unless Customer's Plan Design would otherwise exclude these drugs or Customer notifies AdvancePCS in writing of its objection.
- B. Member Submitted Claims.** AdvancePCS will accept Claims submitted by Members directly to AdvancePCS when such Members submit Claims properly completed on AdvancePCS' standard paper claim form ("**Standard Claim Form**") together with proof of payment. AdvancePCS will process such Claims ("**Direct**" or "**Paper**" Claims) as follows:
- Receive, microfilm and assign a sequential, unique document number to each Standard Claim Form;
  - Data-enter the information from the Standard Claim Form;
  - Perform the system edits described below to the extent information has been made available to AdvancePCS, except that DUR and provider validation edits will not be performed;
  - Produce and mail: Explanation of Benefits ("EOBs") to Members for allowable claims, together with checks for the agreed upon reimbursement amounts; and
  - Produce and mail: Requests for Information ("RFIs") for Claims that are rejected because they are ineligible for payment.
  - Direct or Paper Claims which are not properly completed and require additional processing by AdvancePCS will be subject to the Preprocessed Direct Claims fee set forth in Exhibit B.
- C. System Edits.** For Claims submitted, except as otherwise provided herein, AdvancePCS will perform the following claim edits or such other claim edits as AdvancePCS shall deem proper from time to time:
- Member Eligibility
  - Ineligible Drug
  - Duplicate Prescriptions
  - Provider Validation
  - Incorrect Price

*EXHIBIT A*  
*DESCRIPTION OF SERVICES*

- Plan Design Eligibility
- Missing/Invalid Data
- Managed Access<sup>®</sup> (if applicable)
- DUR (if applicable)
- State Date
- Claim Cost
- Excluded Drug

**D. Taxes.** Customer will pay to AdvancePCS such tax amounts as submitted by pharmacies for Covered Items dispensed to Members.

**E. Medicaid Processing.** Customer acknowledges that Medicaid agencies may submit Claims for, on behalf of and/or in the name of a Member and such Claims will be treated as any other Claims from Members; provided, however, that (i) the amount paid to such Medicaid agency will be the lesser of the amount invoiced by the agency or the amount AdvancePCS would have reimbursed a Member for such Claim in accordance with the Plan Design, and (ii) the Administrative Fee for processing Claims submitted by Medicaid agencies will be invoiced at the rate set forth in Exhibit B. Any amounts paid by AdvancePCS to Medicaid agencies will be deemed benefits under the Plan Design, and Customer will pay AdvancePCS for such amounts in accordance with Section 2.2 of the Agreement.

**5. DRUG UTILIZATION REVIEW ("DUR")**

**A. QUANTUM Alert<sup>®</sup> Services.** AdvancePCS will provide its QUANTUM Alert automated concurrent DUR Services for POS transactions. The QUANTUM Alert system currently includes edits relating to excessive utilization; drug-drug interactions; therapeutic duplications; insufficient drug doses; excessive drug doses; drug-age conflicts; drug-pregnancy advisories; drug-disease contraindications; late refills; and controlled substance issues.

If a POS transaction fails the excessive utilization edit, AdvancePCS will send to the pharmacist an on-line message indicating Claim denial and an "Excessive Utilization" alert.

In certain instances, a Claim that is denied for excessive utilization may actually represent appropriate drug therapy as determined by the applicable physician or pharmacist in his/her professional judgment. For example, the early refill may be necessary because of an increase in dose, change in prescribing instructions, etc. In these instances, the pharmacist will exercise his/her professional judgment to either (i) dispense the prescribed drugs and instruct the Member to submit a Direct Claim for reimbursement or (ii) call AdvancePCS and direct AdvancePCS to override the denial edit.

Clinical and quality of care issues detected by the other DUR edits do not affect Claim payment, but result in transmission of a warning or alert message transmitted at the time of dispensing to the pharmacist as part of the paid Claim response from AdvancePCS. Network Providers are directed to review the Quantum Alert messages as they are received and to use their professional judgment as to whether action is required.



*DESCRIPTION OF SERVICES*

- B. Retrospective DUR Services.** AdvancePCS will provide to Customer AdvancePCS' retrospective DUR services, including RxReview<sup>®</sup> and Clinical Consulting. Such services are designed to provide useful clinical information to physicians, and include written communications as well as personal visits with physicians by AdvancePCS' Clinical Specialists. These communications to physicians include summaries of current clinical studies, formulary recommendations, and may include patient profiles and targeted interventions. Customer has or will obtain any authorizations required by Law, and will make all disclosures required by Law, for AdvancePCS to perform the retrospective DUR services.
- C. Rebate Related Services.** To obtain Rebates from Manufacturers, AdvancePCS will provide, on behalf of Customer, AdvancePCS' Retrospective DUR Services as described in Section 5B. AdvancePCS also will make available its quarterly physician newsletter for distribution to physicians by Customer. At Customer's request, Customer's logo or other identification may be incorporated into the newsletters. If Customer adopts a Custom Formulary, Customer will be responsible for distributing these newsletters, and completing and returning to AdvancePCS a Verification of Distribution form, which may be required by certain Manufacturers as a condition of paying Rebates. If Customer adopts AdvancePCS' National Formulary, AdvancePCS will be responsible for the distribution of these newsletters to physicians, and to provide Manufacturers with verification of such distribution, as may be necessary.

In addition to these Services, AdvancePCS may propose other interventions that are designed to increase Rebates and/or reduce the costs of Covered Items under this Agreement. Customer may decline to allow such interventions, but AdvancePCS will not be responsible for any loss of economic benefit that results from the failure to implement the proposed interventions. Nor will AdvancePCS be liable if any Manufacturer refuses to pay Rebates as a result of Customer's failure to distribute physician newsletters or other communications recommended by AdvancePCS, or Customer's failure to complete and return to AdvancePCS a Verification of Distribution form.

- D. Limitations.** The information generated in connection with DUR Services is intended as an economical supplement to, and not a substitute for, the knowledge, expertise, skill, and judgment of physicians, pharmacists, or other health care providers in patient care. Providers are individually responsible for acting or not acting upon information generated and transmitted through the DUR Services, and for performing Services in each jurisdiction consistent with the scope of their licenses. Except as set forth in Section 5B above, in performing DUR Services, AdvancePCS will not, and is not required by this Agreement to deny Claims or require physician, pharmacist or patient compliance with any norm or suggested drug regimen, or in any way substitute AdvancePCS' judgment for the professional judgment or responsibility of the physician or pharmacist.

AdvancePCS' DUR Services are highly automated. Any focused professional review would also be based upon automated analysis of Member's profiles. Therefore, the DUR Services are necessarily limited by the amount and type of patient information available to AdvancePCS. Meaningful patient information which may not be available to AdvancePCS includes, but is not limited to, patient diagnoses, utilization of drugs obtained without utilizing the RECAP System or otherwise not included in the patients'



*EXHIBIT A*  
*DESCRIPTION OF SERVICES*

profile or Claim data. AdvancePCS will have no obligation to acquire information concerning any patient beyond the information that is included in Customer's eligibility records or the Claim data submitted by Network Providers in connection with the Plan.

AdvancePCS will update DUR databases on a reasonable basis to reflect changes in available standards for pharmaceutical prescribing; provided, however, no database will contain all currently available information on accepted medical practice or prescribing practices.

**6. PERFORMANCE RX® PROGRAM**

Under AdvancePCS' Performance Rx® prescription management program, AdvancePCS and the Network Providers will work together to encourage the use of Preferred Drugs by (i) identifying appropriate opportunities for converting a prescription from a non-Preferred Drug to a Preferred Drug, and (ii) contacting the Member and the prescriber to request that the prescription be changed to the Preferred Drug. A Preferred Drug is one on the Performance Drug List, which has been developed by AdvancePCS as a clinically appropriate and economically advantageous subset of the AdvancePCS clinical formulary, as revised by AdvancePCS from time to time.

**7. MANAGED ACCESS® MANAGED DRUG LIMITATIONS**

**A. Rejection of Claims Requiring Prior Authorization.** Under AdvancePCS' Managed Access program, for those drug/Member situations, which are identified as requiring a coverage override, AdvancePCS will reject all Claims submitted unless a Managed Access record has been entered into AdvancePCS' system. The Managed Access record will allow for overrides of:

- Plan Design parameters
- Drugs requiring prior authorization

**B. Limitation of Dispensing to Specific Providers.** Under AdvancePCS Managed Access program, for those drug/Member situations that are identified as requiring an access limitation, AdvancePCS will authorize only those Claims submitted by specified providers for which a Managed Access record has been entered into AdvancePCS' system.

The Managed Access record will allow for lock-ins to:

- A specific physician
- A specific pharmacy
- A specific chain

The Managed Access record will allow for lock-ins to these specific providers for:

- All drugs
- Drugs at:
  - The GC (Generic Class Number)
  - The UC (Uniform System of Classification)
  - The ND (National Drug Code)
  - The LS (Legal Structure)

**DESCRIPTION OF SERVICES**

- C. **Managed Access/Record.** Customer will notify AdvancePCS of Members for whom an authorization has been made by completing a Managed Access enrollment form. Upon the establishment of prior authorization record for a Member and payment of applicable fees, future Claims for that Member and the specified drug or drug class, as the case may be, will be processed and paid until the expiration of the authorization record.
- D. **Managed Drug Limitations.** Under AdvancePCS' Managed Drug Limitations ("MDL") program, limitations on drug coverage may be established for categories of drugs, which are otherwise included in the Plan Design or are included subject to coverage override, as described above. Claims for these drugs will be rejected if dispensing the drugs would cause any applicable MDL to be exceeded. MDLs may be established by various criteria, including specified time periods, accumulations, and/or Claims types.
- E. **Limitation on Services.** Customer acknowledges that AdvancePCS' Managed Access and Managed Drug Limitations programs are automated non-discretionary processing techniques intended to provide better management of Customer's drug benefits based on objective criteria and the limited amount of patient information available to AdvancePCS. AdvancePCS will not undertake, and is not required hereunder, to determine medical necessity, appropriateness of therapies, to make diagnoses or substitute AdvancePCS' judgment for the professional judgment and responsibility of the physician. Any action taken by AdvancePCS authorizing or denying Claims for those drugs requiring coverage override will be pursuant to written instructions received from Customers.

**8. PRIOR AUTHORIZATION/FORMULARY EXCEPTION ("PA/FE")**

AdvancePCS agrees to provide Customer with a form of prospective drug utilization review known as the PA/FE Program. AdvancePCS will supply a list of suggested criteria for review, modification and/or adoption by Customer. Customer will have final approval over the criteria to be utilized, which will be evidenced by a writing signed by Customer. AdvancePCS will administer the criteria as approved by Customer. If Customer does not wish to accept the proposed changes to the PA criteria, Customer agrees to notify AdvancePCS in writing within ten (10) business days and may terminate this Agreement, pursuant to Section 8.2.2 of this Agreement or adopt the customized criteria for a mutually agreed upon fee. Customer shall be deemed to have approved any proposed changes to the criteria unless it notifies AdvancePCS in writing of its objection.

AdvancePCS will accept PA/FE requests from physicians and will approve or deny such requests in accordance with the PA/FE criteria approved by Customer. AdvancePCS will make clinical pharmacists available to provide professional support to the PA/FE unit as AdvancePCS determines necessary to evaluate PA/FE requests and clarify Customer's PA/FE criteria. AdvancePCS' PA/FE unit will notify the physician who submitted the PA/FE request of the coverage determination for such request.

Approvals will be entered in the appropriate AdvancePCS claim management system. AdvancePCS' clinical pharmacists will review denials on a regular basis, to assist Customer in determining whether PA/FE criteria and/or processes warrant modification. Denial reports will be furnished to Customer upon request for decisions regarding updates to PA/FE criteria.

*EXHIBIT A*  
*DESCRIPTION OF SERVICES*

Reports of approvals and denials will be produced on a quarterly basis and included in quarterly reporting to Customer.

**9. MAC SELECTION**

Customer may choose from among various options for the administration of Customer's MAC program. Depending upon the option selected, Customer may specify whether or not the Member will pay the difference in cost (in addition to any applicable copayment) when the Member request to have a brand dispensed when a generic equivalent is available. Customer may also specify whether Customer or the Member will pay the difference in cost when a brand is dispensed because the prescribing physician has indicated "dispense as written".

**10. MANAGEMENT REPORTING**

**A. Standard Management Reports.** AdvancePCS will provide Customer with AdvancePCS' standard management reports in connection with the Services provided hereunder, which reports may change from time to time at AdvancePCS' discretion. Customer may elect to receive some or all of the standard management reports made available by AdvancePCS.

**B. On-Line Data Reporting/Editing.** AdvancePCS will make available to Customer AdvancePCS' Client On-Line Inquiry System, pursuant to which Customer will have on-line access to inquire, update Plan Design information, and, if applicable, input Claims. Customer is responsible for providing any hardware necessary for access to the Client On-Line Inquiry System and for paying all fees for telecommunication access.

Customer agrees that AdvancePCS may rely on information entered into the Client On-Line Inquiry System through the use of a Log-On ID. Customer further agrees to indemnify AdvancePCS for, from and against any and all costs, losses or damage that arise, or are alleged to arise, (i) as a result of such reliance by AdvancePCS or (ii) out of Customer's use of the Client On-Line Inquiry System.

Customer will comply with all rules AdvancePCS establishes from time to time in connection with the On-Line Services and sign any addendum required by AdvancePCS for the use of such Services. Direct or Paper Claims submitted On-Line will be subject to the Paper Claim Direct Submission fee set forth in Exhibit B.

**11. FORMULARY SERVICE**

Upon request from Customer, AdvancePCS will perform the following Services (the "Formulary Services") for the fees set forth on Exhibit B attached hereto.

**A. Establishment of Formulary.** AdvancePCS will work with Customer to effect the adoption, distribution and implementation of a drug formulary based on the AdvancePCS formulary (the "Formulary"). AdvancePCS and Customer will use diligent efforts to ensure the prompt adoption and distribution of the Formulary. Charges for AdvancePCS' production and distribution or shipping of Formulary are set forth in Exhibit A.

*EXHIBIT A*  
*DESCRIPTION OF SERVICES*

- **AdvancePCS' Clinical Formulary and Prescribing Guidelines ("National Formulary").** For customers adopting AdvancePCS' National Formulary as the Formulary, AdvancePCS will distribute each edition of the Formulary and updates to its providers.
  - **Custom Formulary.** For customers utilizing a custom formulary, AdvancePCS will ship the custom formularies to Customer. Customer will use diligent, good faith efforts to ensure the prompt distribution of the formulary and updates to its chosen providers. The cost of postage and distribution of the formulary and any subsequent updates thereto or reports hereunder, to Customer's chosen providers, will be borne by Customer. If Customer fails to distribute such formulary updates in a timely manner, Customer will be liable to AdvancePCS for any loss of Rebates and will hold AdvancePCS harmless for, from and against the same.
- B. Updating of Formulary.** AdvancePCS will work with Customer to provide for the annual review, updating, and distribution of the Formulary, to address changes to the Formulary made desirable by changes in the pharmaceutical industry, new legislation and regulations, the experience of Customer and its providers with the Formulary, current medical literature and new recommendations developed by AdvancePCS based on its research and experience.
- C. Rebate Related Utilization Review.** To obtain Rebates from Manufacturers, AdvancePCS will perform on behalf of Customer, AdvancePCS' Retrospective DUR program as described in Section 5C.
- In addition to the Retrospective DUR Program, AdvancePCS may propose other interventions from time to time which are designed to increase Rebates and/or reduce the costs of Covered Items under this Agreement. Customer may decline to allow such interventions, but in such event AdvancePCS will not be responsible for any loss of economic benefit which results from the failure to implement the proposed interventions.
- D. Rebate Contracts.** AdvancePCS will attempt to contract with certain Manufacturers for Rebate programs. Customer acknowledges that whether and to what extent Manufacturers are willing to provide Rebates to Customers will depend upon the Plan Design adopted by Customer, and other aspects of Customer's Plan Design, as well as AdvancePCS receiving sufficient information regarding each Claim submitted to Manufacturers for Rebates.
- E. Other Rebate Arrangements.** With respect to Members covered under this Agreement, Customer will not participate in any other formulary or similar discount program (including any such program which may be available through a mail order pharmacy designated by Customer) during the term of the Agreement and will not itself create any formulary during the term of the Agreement. Also, with respect to such Members, Customer agrees not to enter into any direct or indirect contracts with pharmaceutical Manufacturers for discounts during the term of the Agreement or any extension thereof. Nothing in this section will prohibit Customer from entering into arrangements with other pharmaceutical management companies offering formulary Services after the term of the Agreement.
- F. Rebates.**

*EXHIBIT A*  
*DESCRIPTION OF SERVICES*

- On behalf of Customer, AdvancePCS will receive the Rebates paid by Manufacturers to Customer. AdvancePCS will make payments of such Rebates once each calendar quarter as follows: within 60 days of the beginning of each quarter, AdvancePCS will pay to Customer all Rebates received by AdvancePCS during the prior quarter, if any, net of the fees retained by AdvancePCS pursuant to Section 2.
- Along with each payment of Rebates, AdvancePCS will provide a report to Customer that includes the Manufacturer's name, the number of prescriptions and/or amount of dollar purchases for each Manufacturer, and the total amount of Rebates paid by each Manufacturer.
- Upon reasonable prior written notice, AdvancePCS agrees that an independent third party, at Customer's expense, will have the right, subject to reasonable business limitations, to audit volume discount contracts from Manufacturers from time to time, provided that Customer will give AdvancePCS adequate assurance, which may include at AdvancePCS' option the signing of a confidentiality agreement by Customer and the independent third party, that Customer and such third party will hold in confidence any information obtained through the audit. AdvancePCS will make the contracts available for such auditing purposes at its offices during normal hours of operation.
- As consideration for the Formulary, the negotiation, collection and distribution of Rebates and other Services provided by AdvancePCS under this Agreement, Customer will pay to AdvancePCS a fee in an amount equal to the percentage set forth in Exhibit B multiplied by the Rebates collected by AdvancePCS in connection with this Agreement. In lieu of billing Customer for the fees provided for in this section, AdvancePCS may retain those amounts from any Rebates collected by AdvancePCS on behalf of Customer in connection with this Agreement.

## 12. PERFORMANCE MAIL OR OTHER STANDARD ADVANCEPCS MAIL PROGRAM

**Services.** AdvancePCS will provide to Customer AdvancePCS' Performance Mail Program or other standard AdvancePCS Mail Program that includes mail order pharmacy Services which are provided by AdvancePCS Mail. AdvancePCS may make changes to such program from time to time so long as such changes do not materially alter any of the provisions of this document.

AdvancePCS will provide to Customer, and Customer will distribute to Members, program start-up kits which explain to Members how to use the program, and such other materials as Members will require to begin using the program.

AdvancePCS Mail will receive prescriptions from Members via the U.S. mail or commercial carrier at an address(es) specified by AdvancePCS from time to time. Subject to and in accordance with the Plan Design and applicable Law, AdvancePCS Mail will dispense Covered Drugs in accordance with those prescriptions and mail the Covered Drugs to Members at addresses designated by such Members, so long as such addresses are located in the United States.

AdvancePCS Mail will provide to Members toll-free telephone access to a pharmacist and

*EXHIBIT A*  
*DESCRIPTION OF SERVICES*

customer service representative. Access to a pharmacist pursuant to the foregoing will be available to Members twenty-four (24) hours per day, seven (7) days per week. The fee for this toll-free telephone access is included in the base fee for AdvancePCS Mail Service, when applicable.

For Covered Items provided by AdvancePCS through the AdvancePCS Performance Mail Program or other standard AdvancePCS Mail Program, Customer will pay to AdvancePCS the amount set forth on Exhibit B hereto. Certain drugs that become available on the market from time to time will not be subject to the contracted rate for prescription Claims due to, among other things, specialized manufacturer processes, limited availability or extraordinary shipping requirements and may not be available through AdvancePCS Mail. Such drugs presently include biotechnology drugs such as Betaseron and Avonex and compounds. AdvancePCS will provide Customer with a list of such drugs, and their corresponding rates (which are generally no less than full AWP), upon request. AdvancePCS Mail will dispense these drugs to Members unless Customer's Plan Design would otherwise exclude these drugs or Customer notifies AdvancePCS in writing.

Customer acknowledges that AdvancePCS Mail may from time to time to engage in therapeutic interchanges in accordance with applicable Law.

AdvancePCS Mail will dispense drugs even if the prescription is not accompanied by the correct copay/deductible/coinsurance amount and Customer will be liable to AdvancePCS for such amounts if reasonable collection efforts by AdvancePCS fail.

**13. OTHER ADDITIONAL SERVICES**

Upon request from Customer, AdvancePCS will perform the following Services for the fees set forth on Exhibit B attached hereto.

- A. **Paper Eligibility Submission.** AdvancePCS will maintain eligibility information regarding Members submitted by Customer in a manual form (other than tape or telecommunication) from time to time.
- B. **Decentralized Administration.** AdvancePCS will provide Customer with client service support to more than one Customer contact or location.
- C. **Claim Detail Report via Paper.** AdvancePCS will provide Customer with a printout of AdvancePCS' standard Claims Detail Report.
- D. **Card Reissuance.** AdvancePCS will reissue cards for Members upon request. If cards are reissued, Customer will pay the fee set forth in Exhibit B.
- E. **CAT/BAT.** AdvancePCS will provide Customer with detailed Claim and/or administrative billing information through AdvancePCS' standard claims activity transmission or tape ("CAT") and/or AdvancePCS' standard billing activity transmission or tape ("BAT"). Charge for recreated/historic tapes will be quoted upon request.
- F. **Custom CAT/BAT.** If Customer requests a custom CAT/BAT, AdvancePCS will charge Customer the standard hourly rate set forth in Exhibit B for such custom CAT/BAT.

*EXHIBIT A*  
*DESCRIPTION OF SERVICES*

- G. **Case Set-Up.** Customer may submit a written request to establish one or more new groups under Customer's Plan Design. Customer will pay AdvancePCS the Case Set-Up fee for each new group that AdvancePCS establishes for Customer.
- H. **Carrier/Group Rebate Reports on Tape.** AdvancePCS will provide Customer with a detailed Carrier/Group Rebate tape through AdvancePCS' standard Carrier/Group layout.
- I. **Customer-Specific Programming.** If Customer will request Services or changes to Services that require customized programming or systems work, AdvancePCS will attempt to estimate to Customer the time and cost for completion of such work. If Customer authorizes AdvancePCS to perform such work, Customer will pay AdvancePCS the cost of performing such work at the programming rate set forth on Exhibit B.



*EXHIBIT B*  
*ADMINISTRATIVE FEES*

**Massachusetts State Carpenters**  
**Effective April 1, 2001**

As consideration for the Services selected by Customer pursuant to the Implementation Documents and described in Exhibit A, Customer will pay to AdvancePCS the fees set forth below:

<u>Base Services</u> - Per Paid POS Claim	\$0.19 <sup>1</sup>
Performance or other standard AdvancePCS Mail Program	\$0.00 <sup>1</sup>

Retail Claim Rates<sup>2</sup>

Brand:	AWP-15% + \$2.00 dispensing fee
Generic:	AWP-15% + \$2.25 dispensing fee or MAC + \$2.25 dispensing fee, whichever is applicable

Mail Service Claim Rates

Brand:	AWP- 18% + \$0.00 dispensing fee
Generic:	AWP- 40% + \$0.00 dispensing fee

Member Submitted Claim Rates (Unless specified otherwise in Implementation Documents)

Brand:	AWP-15% + \$2.50 dispensing fee
Generic:	AWP-15% + \$2.50 dispensing fee or MAC, whichever is applicable

Additional Services

	<u>Fee</u>
Section 2 - Member Service/Toll Free Member Services	\$.13/Claim <sup>3</sup>
Section 4B - Paper Claim Direct Submission	\$1.50/Claim
Section 4B - Preprocessed Direct Claims	\$2.50/Claim
Section 4E - Medicaid Claim tape submission	\$1.50/Claim
Medicaid Claim paper submission	\$2.50/Claim
Section 7 - Managed Access/Managed Drug Limitations	\$2.50 Per Authorization <sup>4</sup>
Section 8 - Prior Authorization/Formulary Exception (PA/FE)	\$30.00/Request <sup>5</sup>
Section 10B - Paper Claim Direct Submission (on-line)	\$.80/Claim
Section 11A - Production, Postage, and Distribution Costs for Formulary Booklets and Physician Newsletters	Included in Base
Section 11F - AdvancePCS' Rebate Percentage	Anything over \$1.15 <sup>6</sup>
Section 12 - Mail Service Claims	See above
Section 13A - Paper Eligibility Submission	\$.02/Claim
Section 13B - Decentralized Administration	\$.02/Claim
Section 13C - Claim Detail Report via Paper	\$.02/Claim
Section 13D - Card Reissuance	\$.50/Card
Section 13F - Custom CAT/BAT Tapes	Subject to Customer Specific Programming charge
Section 13G - Case Set-Up	\$20.00/Group
Section 13H - Carrier/Group Rebate Reports on Tape	\$100.00/Each
Section 13I - Customer Specific Programming	\$110.00/Hour

Note: Charges not identified above will be quoted upon request.

Finance Charges: Invoices are assessed finance charges at the rate of 1.5% per month on the amounts not paid within terms of the Agreement.

[Continued on Next Page]



*EXHIBIT B*  
*ADMINISTRATIVE FEES*

**Additional Payment Terms:**

1. New Base Administrative Fee to be effective January 1, 2001.
2. The retail rates represent the overall network rates delivered for groups with plan designs that do not require hardcoding.
3. If Customer utilizes AdvancePCS Mail and Retail services, this \$.13 fee will not apply.
4. If Managed Access record is entered by Customer "on-line", this \$2.50 fee will not apply.
5. AdvancePCS will provide the first 200 requests for Prior Authorization at no charge to the client. Upon completion of the first 200 requests, AdvancePCS will charge Customer \$30.00 per request as set forth above.
6. **Rebate Guarantee:** AdvancePCS guarantees that Customer's share of Rebates shall be one dollar and fifteen cents (\$1.15) per paid Retail and Mail Claim (the "Guaranteed Rebate Amount"). In the event that Rebates collected are less than the Guaranteed Rebate Amount, AdvancePCS shall pay to Customer the amount of any deficiency; provided, however, that if at any time during the term of this Agreement, AdvancePCS' ability to collect Rebates under its Rebate contracts with Manufacturers, either currently in existence or entered into after the date of this Agreement, is materially adversely impacted by legislative, regulatory, judicial action, or a change in drug industry practice, AdvancePCS shall be released from its obligation to pay the Guaranteed Rebate Amount hereunder and shall be required to pay Customer only Customer's share of the actual Rebates collected. This Rebate guarantee will be in effect for the period beginning April 1, 2001, and ending March 31, 2002, and is contingent upon Customer's acceptance of and continued participation in AdvancePCS Mail with Customer's current Plan design parameters. For subsequent years, any Rebate guarantee will be determined by annual negotiation by the parties of a mutually acceptable Guaranteed Rebate Amount based on projected market estimates.

All prices are contingent upon Customer's current Plan design, full adoption of AdvancePCS' Performance Drug List, and formulary management and intervention programs, as well as representations made by Customer regarding Member enrollment and utilization of pharmacy services.

Customer is in all events responsible for any postage costs or other mailing and handling-related costs (including, without limitation, mailing charges associated with Explanation of Benefits or Requests for Information) incurred by AdvancePCS in connection with the provision of Services or additional services.

EXHIBIT C  
PERFORMANCE STANDARDS

**Definitions and Limitations Applicable to the Performance Standard**

The proposed performance standards are subject to the definitions and limitations set forth in Definitions and Limitations descriptions below.

**Definitions:**

For purposes of the performance standards herein, (i) *Agreement* shall mean that certain agreement between a given Customer and AdvancePCS regarding the provision of pharmacy benefit management services, (ii) *Business Day* shall mean AdvancePCS' Normal Business Hours on any day other than (x) a Saturday or Sunday or (y) a day on which AdvancePCS' Scottsdale Location is closed for general business purposes, (iii) a *Force Majeure Event* shall mean an event that prevents AdvancePCS from satisfying a performance standard, in whole or in part, as a result of causes beyond AdvancePCS' reasonable control including, without limitation, acts of God, war, civil disturbance, court order, governmental intervention, Change in Law, nonperformance by Customer's or any third party, failures or fluctuations in electrical power, heat, light, air conditioning or telecommunications equipment, (iv) *Minneapolis Location* shall mean 5701 Green Valley Drive, Minneapolis, Minnesota 55437 or such address that AdvancePCS may notify Customer from time to time, (v) *Normal Business Hours* shall mean 7:00 a.m. Scottsdale, Arizona time through 5:00 p.m. Scottsdale, Arizona time on any given Business Day, which hours may change from time to time in AdvancePCS' discretion and (vi) *Scottsdale Location* shall mean 9501 East Shea Boulevard, Scottsdale, Arizona 85260.

**Limitations:**

AdvancePCS shall diligently attempt to maintain its performance at the levels represented herein; provided, however, that failure to achieve or maintain the levels set forth herein shall not constitute a default for purposes of the termination provisions set forth in the Agreement. The proposed performance standards will be equitably adjusted by the parties to the extent AdvancePCS has suffered a Force Majeure Event during the applicable measurement period.

AdvancePCS shall not be liable to Customer for any failure to satisfy a performance standard during any time that there was no agreement between AdvancePCS and Customer even if a subsequent written agreement between the parties provides that the effective date of the Agreement is prior to the time that such written agreement was actually executed by the parties.

Notwithstanding AdvancePCS' failure to satisfy a performance standard that is measured on an *all AdvancePCS customer* basis, AdvancePCS shall be deemed to have satisfied a performance standard with respect to Customer if it satisfies such standard with respect to Customer only.

AdvancePCS' obligations to meet the performance standards herein are subject to the terms and conditions set forth in the Agreement, and in the event of any conflict between the terms hereof and the terms of the Agreement, the terms of the Agreement shall control and govern the obligations of the parties with respect to such matters.

The maximum amount of penalties that AdvancePCS shall have at risk for any plan year shall be 30% of the total administrative fees for such plan year. The total amount at risk shall be allocated equally among the performance standards. AdvancePCS shall have no liability for any penalty which is asserted by Customer or any third party for AdvancePCS' failure to meet a performance standard more than one (1) year after the end of the relevant measurement period. For purposes of this Exhibit C, Administrative

*EXHIBIT C*  
*PERFORMANCE STANDARDS*

Fees shall mean the Base Fee as listed in Exhibit B. Charges for additional services selected shall not be included in the calculation of penalties.

If AdvancePCS fails to meet the proposed standards, the penalties described herein shall be the sole and exclusive remedy available to Customer for such failure. To the extent permitted by law, any statutory remedies that are inconsistent with the provisions hereof are waived. If any period covered by the Agreement is less than the period covered by the proposed performance standard, and AdvancePCS has not met such performance standard for such period, the penalty associated with such failure shall be prorated to reflect the actual period during which the Agreement was in effect. If requested, AdvancePCS will submit a measurement report to Customer within ninety (90) days after the end of the calendar year. If financial penalties are involved, payment must be requested by Customer in writing within ninety (90) days of receiving the end of year performance guarantee report, and AdvancePCS will make reasonable efforts to pay within ninety (90) days thereafter.

Unless otherwise indicated with respect to a specific performance standard, AdvancePCS' satisfaction of the proposed performance standards shall be (i) monitored internally by AdvancePCS on a monthly basis for all of AdvancePCS' customers in the aggregate which are on the same computer system platform as Customer, (ii) measured by AdvancePCS on a calendar year basis for all of AdvancePCS' customers in the aggregate which are on the same computer system platform as Customer and (iii) reported to customers annually upon customers' prior written request.

#### **SERVICE OPERATIONS**

1. **Member Services.** For customers that elect AdvancePCS' Member Services, telephone inquiries made during Member Services hours from plan members will be answered, on average, in thirty (30) seconds or less by either a representative or an Interactive Voice Response. No more than two percent (2%) of all telephone inquiries during these hours will be abandoned by plan members. Additionally, no more than two percent (2%) of all telephone inquiries during these hours from plan members will be blocked due to AdvancePCS' failure to maintain its system. For purposes of this standard, telephone inquiries shall be deemed abandoned if plan members terminate the call prior to being connected to either a representative or an Interactive Voice Response. Telephone inquiries shall be deemed blocked if plan members are not able to connect to a representative or an Interactive Voice Response.
2. **Member Satisfaction Survey.** Customer satisfaction surveys shall be conducted annually among a random sample of AdvancePCS' entire base of clients, prescription drug benefit participants and participating pharmacists who have contacted an AdvancePCS call center during the survey period. Based upon the respondents' experiences with AdvancePCS call centers, combined overall satisfaction ratings of at least 90% shall be guaranteed.

Surveys shall be conducted by independent market research firms specializing in customer satisfaction issues. AdvancePCS shall be responsible for selection of vendors, survey design, and all costs associated with conducting the surveys.

#### **IMPLEMENTATION**

3. **Implementation.** AdvancePCS will implement customers on its system as of the effective date of the Agreement provided that AdvancePCS receives, within the time frames reasonably requested

*EXHIBIT C*  
*PERFORMANCE STANDARDS*

by AdvancePCS, complete and accurate implementation information from its customers, including, without limitation, any documents signed by its customers that AdvancePCS may reasonably request.

**ADVANCEPCS MAIL SERVICE**

4. **AdvancePCS Mail Service Shipping; Clean Prescriptions.** Ninety-five percent (95%) of all pharmacist-approved Clean Prescriptions (non-Exception Prescriptions) will be shipped within two (2) Business Days after the Business Day such prescription is received. Exception Prescriptions may include, among other things, follow up activities related to drug utilization review issues, and calls to prescribers to clarify or question a prescription order or request approval for a generic substitution or a therapeutic interchange.
5. **AdvancePCS Mail Service Shipping; Exception Prescriptions.** Ninety-five percent (95%) of all pharmacist-approved Exception Prescriptions will be shipped within five (5) Business Days after the Business Day such prescription is received. Exception Prescriptions may include, among other things, follow up activities related to drug utilization review issues, and calls to prescribers to clarify or question a prescription order or request approval for a generic substitution or a therapeutic interchange.
6. **AdvancePCS Mail Service Prescription Accuracy Rate.** The accuracy rate for all mail order prescriptions dispensed to plan members will be at least ninety-nine and ninety-five one-hundredths of a percent (99.95%). Notwithstanding the foregoing, an error will not include immaterial matters such as generic substitution not addressed, incorrect spelling of a plan member's name on label, or incorrect spelling of a physician's name. An error will be deemed to include incorrect patient, inappropriate directions, incorrect strength or incorrect medication in the container.

**ENROLLMENT**

7. **Tape, Cartridge, Diskette, Telecom, Positive File**

Eligibility information submitted to AdvancePCS by its customers in a machine-readable form via a 3420 tape reel, 3480 or 3490 cartridge, or diskette, for the purpose of maintaining the eligibility file will become effective, on average, within two (2) Business Days following the Business Day that AdvancePCS has received complete and accurate information from its customers.

Eligibility information submitted to AdvancePCS by its customers in a machine readable form via telecommunications prior to 1:00 p.m. Scottsdale, Arizona time for the purpose of maintaining the eligibility file will become effective, on average, within two (2) Business Days (which two (2) Business Days shall include the Business Day that such eligibility information is submitted by its customers) after receipt of complete and accurate information by AdvancePCS. For eligibility information submitted in a machine-readable form via telecommunications after 1:00 p.m. Scottsdale, Arizona time on a given Business Day, such eligibility information will become effective, on average, within two (2) Business Days following the Business Day that AdvancePCS has received complete and accurate information from its customers.

*EXHIBIT C*  
*PERFORMANCE STANDARDS*

With respect to eligibility counts of four hundred thousand (400,000) or less, AdvancePCS will compare, if requested, customers' eligibility information as represented in AdvancePCS' database against a submission of customers' entire eligibility file. Such comparison will be completed and any required changes implemented, on average, within two (2) Business Days following the Business Day that AdvancePCS has received complete and accurate information in a machine-readable form from its customers. If the eligibility count is (400,001) or more, AdvancePCS will schedule and perform the compare of customers' eligibility information during non-peak system hours. Such comparison will be completed and any required changes implemented, on average, within four (4) Business Days following the Business Day that AdvancePCS has received complete and accurate information in a machine-readable form from its customers.

AdvancePCS will be excused from its obligation to meet this standard with respect to any submission of eligibility information which (i) is not submitted in a format mutually agreed to by the parties, (ii) is not readable, in whole or in part, due to circumstances beyond the control of AdvancePCS or (iii) includes incomplete, inaccurate or other information which causes questions to arise with respect to the submission.

#### **PHARMACY**

8. **Pharmacy Audits.** Each calendar year AdvancePCS will perform field audits of not less than four percent (4%) of the pharmacies that have entered into a provider agreement with AdvancePCS (AdvancePCS Pharmacies). AdvancePCS will determine the aggregate number of AdvancePCS Pharmacies on January 1 of the calendar year to be measured; such number will only include AdvancePCS Pharmacies that submitted claims for reimbursement to AdvancePCS in December of the preceding calendar year. Such audits will be in accordance with AdvancePCS' current standard targeting and auditing processes, the terms of the Agreement, and the terms of the provider agreement.

#### **NETWORK UTILIZATION MANAGEMENT**

9. **Concurrent DUR Savings.** AdvancePCS guarantees that Customer's savings as a result of The Concurrent DUR program (Quantum Alert®) will be no less than 2% of Customer's drug spend based on the Quantum Alert DUR Cost Savings Report. This guarantee is contingent upon Customer's continuation of PCS' Concurrent DUR program (Quantum Alert®). In the event that the savings achieved are less than 2%, the penalty will be the resulting deficiency.

This guarantee shall be (i) monitored by AdvancePCS quarterly on a Customer-specific basis; and (ii) reported and reconciled to Customer annually upon Customer's written request.

#### **CLAIMS PROCESSING**

10. **Standard Electronic Claims Processing.** One hundred percent (100%) of the claims submitted electronically through the RECAP® system will be priced in accordance with customers' plan guidelines as entered into the RECAP system.

#### **CARD PRODUCTION**

11. **Card Production.** In connection with eligibility updates to bulk and general purpose orders under seven thousand five hundred (7,500) cards, and individual mail orders under three thousand (3,000) cards, AdvancePCS will produce identification cards and deposit such cards in the United States

*EXHIBIT C*  
*PERFORMANCE STANDARDS*

mail, or with another nationally recognized carrier, within, on average, three (3) Business Days following the Business Day that AdvancePCS has received complete and accurate eligibility updates information from its customers and such information has been inputted or updated in AdvancePCS system.

The applicable performance period shall not commence until customers have (i) provided AdvancePCS with the appropriate member addresses and mailing supplies, and (ii) approved the cardstock to be used by AdvancePCS. For purposes of this standard, a bulk order involves mailing identification cards to customers, a general purpose order involves mailing identification cards to customers' groups, and an individual mail order involves mailing identification cards to individual plan members.

AdvancePCS will be excused from its obligation to meet this standard with respect to any identification cards if the corresponding eligibility information (i) is not submitted in a format mutually agreed to by the parties, (ii) is not readable, in whole or in part, due to circumstances beyond the control of AdvancePCS or (iii) includes incomplete, inaccurate or other information which causes questions to arise with respect to the corresponding eligibility information.

**STANDARD REPORTING**

12. **Standard Customer Reporting.** AdvancePCS will mail Customer its standard cycle reports, on average, within fifteen (15) Business Days following the last Business Day of each of AdvancePCS' standard claims processing cycles. AdvancePCS will mail Customer its standard month end reports, on average, within (15) Business Days following the close of the first standard claims processing cycle of the following month. For purposes of these standards, AdvancePCS shall be deemed to have satisfied this standard if AdvancePCS deposits such reports, addressed to Customer, into the United States mail or with another nationally recognized carrier within the applicable time period.

# **Exhibit 16C**



# EXECUTION COPY

## INTEGRATED PRESCRIPTION DRUG PROGRAM MASTER AGREEMENT

THIS AGREEMENT is entered into as of July 1, 2005 (the "Effective Date"), between Medco Health Solutions, Inc., located at 100 Parsons Pond Drive, Franklin Lakes, New Jersey 07417 and The National Labor Alliance of Health Care Coalitions, Inc., located at 91 Fieldcrest Avenue, Raritan Plaza II, P. O. Box 6858, Edison, New Jersey 08818-6858 (hereinafter "ALLIANCE" or "NLAHCC");

WHEREAS, the NLAHCC desires for prescription drug benefit services to be provided to Member Funds under separate agreements to be executed between Medco Health Solutions, Inc., and the applicable Member Fund; and

WHEREAS, Medco Health Solutions, Inc. provides prescription drug benefits programs and, in connection therewith, has established networks of participating retail pharmacies and operates a system for the processing, fulfillment, and payment of claims for prescription drugs furnished by such pharmacies; and

WHEREAS, Medco Health Solutions, Inc.'s Medco By Mail mail order pharmacy subsidiaries are licensed pharmacies which provide prescription drugs via a mail order service; and

WHEREAS, NLAHCC and Participating Member Funds desire to retain the services of Medco Health Solutions, Inc. and its subsidiaries, including Medco, L.L.C., as applicable, which holds TPA licenses in certain states (collectively, "Medco"), to provide a prescription drug benefit program (the "Program") including, but not limited to, retail, mail order, and specialty pharmacy services for eligible persons, point-of-care, physician office communications, and cost containment initiatives developed and implemented by Medco, which may include communications with prescribers, patients and/or participating pharmacies, and financial incentives to participating pharmacies for their participation in such initiatives (collectively, "PBM Services").

NOW, THEREFORE, in consideration of the premises and the mutual covenants contained herein, the parties hereto agree as follows:

### 1. DEFINITIONS

- 1.1. "AWP" means the average wholesale price of the Covered Drug, as set forth in the current price list in recognized sources such as First DataBank's National Drug Data File, or other nationally recognized source determined by Medco, or the direct cost listed in those instances in which only the direct cost is listed. Under the Retail Pharmacy Program, AWP is based on the package size submitted and for Compound Prescriptions is 1.25 times the AWP of the submitted Covered Drug. Under the Mail Order Pharmacy Program, AWP is based on package sizes of 100 units for capsules and tablets, 16 oz. quantities for liquids and the manufacturer's smallest available package size for injectable Covered Drugs (or the next closest package size if such quantities or sizes are not available), and all other Covered Drugs will be priced as individual units or smallest package size available (e.g., per vial, per suppository, etc.). If First DataBank or other applicable source changes the methodology for calculating AWP in a way that materially changes the economics of the Program, the parties agree to modify the Program Pricing Terms to preserve the parties' relative economics before such changed methodology.
- 1.2. "Brand Name Drugs" means all single-source drugs and multisource brand drugs as set forth in First Databank's National Drug Data File (or such other nationally recognized source reasonably determined by Medco).
- 1.3. "Coalition" means one of the member organizations that comprise the NLAHCC.



- 1.4. "Compound Prescription" means a prescription that meets the following criteria: two or more solid, semi-solid, or liquid ingredients, at least one of which is a Covered Drug, that are weighed or measured then prepared according to the prescriber's order and the pharmacist's art.
- 1.5. "Contract Year" means the full twelve (12) month period commencing on the Effective Date, and each full consecutive twelve (12) month period thereafter that this Agreement remains in effect.
- 1.6. "Copayment" and/or "Coinsurance" means the amount to be paid by an Eligible Person for each prescription or authorized refill as determined in accordance with the Plan Design(s).
- 1.7. "Covered Drugs" means drugs which, under state or federal law, require a prescription, including Compound Prescriptions. Excluded from Covered Drugs are: (i) cosmetic drugs; (ii) appliances, devices, bandages, heat lamps, braces, splints, and artificial appliances; (iii) health and beauty aids, cosmetics and dietary supplements ("Exclusions"); and (iv) OTC products. Additional Covered Drugs and/or Exclusions applicable to any Participating Member Fund shall be designated by the Participating Member Fund in its applicable Plan Design.
- 1.8. "Dispensing Fee" means the amount payable by each Participating Member Fund through Union Labor Life pursuant to Sections 1, 2, or 3 of Schedule A of this Agreement for a Participating Pharmacy or Medco to dispense a prescription or authorized refill to an Eligible Person.
- 1.9. "Eligible Person" means each person who, through affiliation with a Participating Member Fund of the NLAHCC, is eligible for prescription drug benefits pursuant to this Agreement and the Member Fund Addendum with Medco, and such person's qualified dependents.
- 1.10. "Generic Drug" means a multisource generic drug as set forth in First Databank's National Drug Data File, or such other nationally recognized source, as reasonably determined by Medco, that is available in sufficient supply from multiple manufacturers.
- 1.11. "Group" means a corporation, association, or other entity or group of individuals that is a subset of or is the Member Fund that has a contract or other arrangement in effect with NLAHCC through which the Eligible Persons covered under such Group are entitled to prescription drug benefits pursuant to this Agreement.
- 1.12. "Mail Order Pharmacy Program" means the program described in Section 5 in which Eligible Persons may submit a prescription along with the applicable Copayment/Coinsurance to Medco for dispensing via mail order.
- 1.13. "Integrated Program" means a program in which Eligible Persons enrolled in such program may have prescriptions dispensed either (i) by a Participating Pharmacy under the Retail Pharmacy Program or (ii) by Medco under the Mail Order Pharmacy Program. Reference to the Retail Pharmacy Program and/or Mail Order Pharmacy Program herein will include services performed by Medco for Eligible Persons enrolled in the Integrated Program.
- 1.14. "MAC" or the "Maximum Allowable Cost" consists of a list of off-patent drugs subject to maximum allowable cost payment schedules developed or selected by Medco. The payment schedules specify the maximum unit ingredient cost payable by a Participating Member Fund through Union Labor Life for drugs on the MAC list. The MAC list and payment schedules are frequently updated.
- 1.15. "Member Fund" means any Taft Hartley Welfare Fund or other Group as may be permissible under the by-laws of the NLAHCC which is or may be accepted into the NLAHCC as a member by virtue of its association with or membership in a member organization that comprises the NLAHCC.

- 1.16. "Member Fund Addendum" means the executed addendum, in the form attached as Schedule C, between Medco and a Participating Member Fund pursuant to which Eligible Persons affiliated with such Member Fund receive prescription drug benefits from Medco.
- 1.17. "Member Fund Contract Year" means the full twelve (12) month period commencing on the effective date of the Member Fund Addendum, and each full consecutive twelve (12) month period thereafter that the Member Fund Addendum remains in effect.
- 1.18. "Participating Member Fund" means a Member Fund that has executed a Member Fund Addendum.
- 1.19. "Participating Pharmacy" means a retail pharmacy that has entered into an arrangement with Medco that specifies the terms and conditions of the pharmacy's participation in Medco's retail networks servicing NLAHCC's Program, including the rates that Medco will pay the pharmacy.
- 1.20. "Plan Design" means Program drug coverage, days supply limitation, Copayment/Coinsurance, Formulary (including Formulary drug selection and relative cost indication) and other Program specifications applicable to the Program designated by NLAHCC as set forth in this Agreement or Member Fund Addendum or otherwise documented between the parties.
- 1.21. "Primary Eligible Participant" means each Eligible Person, excluding Eligible Persons who are qualified dependents.
- 1.22. "Program Pricing Terms" means the (i) financial or pricing terms set forth in this Agreement, and (ii) Formulary management fee, Formulary Rebates, Formulary Savings, and the Guaranteed Savings set forth in Section 6 of this Agreement.
- 1.23. "Retail Pharmacy Program" means the program described in Section 4 in which Eligible Persons may purchase Covered Drugs from a Participating Pharmacy upon verification of Program eligibility and payment of the applicable Copayment/Coinsurance, and the claim is submitted by the Participating Pharmacy to Medco for payment in accordance with this Agreement and the applicable Medco Participating Pharmacy agreement.
- 1.24. "TelePAID® System" or "TelePAID®" means Medco's real time, on-line system for adjudicating prescription drug claims submitted by retail pharmacies.

## **2. MEMBER FUND PARTICIPATION**

NLAHCC has selected Medco to provide prescription drug benefit services to its Member Funds. NLAHCC has selected Union Labor Life to offer to its Member Funds the services provided by Medco under this Agreement, including Schedule D (Participating Member Funds Criteria), including Union Labor Life coordinating with Member Funds all eligibility and Program Service issues and communicating those issues and that information to Medco. Upon execution of a Member Fund Addendum by Medco and the applicable Member Fund, Medco will provide prescription drug services to Eligible Persons in the Participating Member Fund through Union Labor Life.

## **3. FURNISHED INFORMATION**

Each Participating Member Fund will promptly furnish to Union Labor Life, in a format acceptable to Medco, all information necessary for Medco to render the services set forth herein. Such information will include, but is not limited to:

- 3.1. The name of each Group and whether such Group will be enrolled under the Retail Pharmacy Program, Mail Order Pharmacy Program or Integrated Program.

- 3.2. The commencement date and termination date of coverage for each Group.
- 3.3. A file of each Group's Eligible Persons, and subsequent timely additions and deletions to such file as changes occur. Each Participating Member Fund through Union Labor Life will pay for any Covered Drug dispensed to a person reported by the Participating Member Fund to Union Labor Life as no longer an Eligible Person, if such notification is not received by Medco at least two (2) full business days prior to the dispensing date of such prescription.
- 3.4. Designation, in writing, of those Plan Design features to be determined by each Participating Member Fund through Union Labor Life for each Group.
- 3.5. The reimbursement terms applicable to direct reimbursement claims submitted by Eligible Persons under the Retail Pharmacy Program.
- 3.6. The type, number and description of Medco identification cards ("Identification Cards") required for each Group enrolled in the Retail Pharmacy Program.

#### 4. RETAIL PHARMACY PROGRAM

The specific features of the Retail Pharmacy Program are as follows:

- 4.1. Program Coverage - The Program coverage (Covered Drugs/Exclusions) and days supply limitation for each Group covered under the Retail Pharmacy Program will be as set forth in each Group's applicable Plan Design designated by each Participating Member Fund in its Member Fund Addendum. Up to a thirty (30) day supply of Covered Drugs per prescription or refill may be dispensed under the Retail Pharmacy Program.
- 4.2. Participating Pharmacy Networks - Medco Health will maintain a Participating Pharmacy Network reasonably necessary to provide services under the Retail Pharmacy Program. Medco will assume the risks associated with negotiating pricing terms with Participating Pharmacies. Medco will be responsible for any amounts that it owes to Participating Pharmacies that exceeds the reimbursement it receives from Union Labor Life on behalf of Member Funds as specified in Section 1 of Schedule A. Medco will retain any reimbursement that it receives from Union Labor Life on behalf of Member Funds, as specified in Section 1 of Schedule A that is in excess of the amounts it is obligated to pay to Participating Pharmacies.
- 4.3. Identification Cards - Medco will (i) produce Identification Cards for those Eligible Persons designated by each Participating Member Fund, with an accompanying explanatory brochure, and (ii) make direct reimbursement claim forms available through the [www.medco.com](http://www.medco.com) internet site for use by Eligible Persons who have not received their Identification Cards, or have had them lost or stolen. Medco will distribute Identification Cards and claim forms to the designated Eligible Persons. All costs associated with distributing and/or mailing such materials are the responsibility of each Participating Member Fund.
- 4.4. Claim Adjudication - Medco will adjudicate claims for prescription drug benefits in accordance with Medco's TelePAID System and the applicable Plan Design. Disapproved claims will be transmitted via TelePAID to the submitting pharmacy with a brief explanation of the cause or causes for disapproval. Should a Participating Member Fund determine that a previously disapproved claim should be approved, and so direct Medco, adjudication of the claim will be accomplished promptly by Medco. Medco is obligated to pay Participating Pharmacies for all claims adjudicated through the TelePAID System. Union Labor Life on behalf of each Participating Member Fund will pay Medco for these claims pursuant to Schedule A, Section 1. Medco will promptly refer to Participating Member Fund all non-routine inquiries by insurance departments, attorneys, claimants, or other persons following the denial of any claims.

- 4.5. Administrative Services - Medco will provide, as applicable, the Base Administrative Services and the Additional Administrative Services set forth in Schedule A.
- 4.6. Pricing - The Program Pricing Terms applicable to the Retail Pharmacy Program are set forth in Schedule A, in addition to the Total Rebates and Guaranteed Rebates set forth in Section 6 of this Agreement.

## 5. MAIL ORDER PHARMACY PROGRAM

### 5.1. Program Coverage

- 5.1.1. The Program coverage (Covered Drugs/Exclusions) and days supply limitation for each Group covered under the Mail Order Pharmacy Program will be as set forth in each Group's applicable Plan Design designated by the Participating Member Fund in its Member Fund Addendum.
- 5.1.2. Medco's mail order pharmacies will not be required to dispense prescriptions for greater than a ninety (90) day supply of Covered Drugs per prescription or refill, subject to the professional judgment of the dispensing pharmacist, limitations imposed on controlled substances, and manufacturer's recommendations. Prescriptions may be refilled providing the prescription so states. Prescriptions will not be filled: (i) more than twelve (12) months after issuance; (ii) more than six (6) months after issuance for controlled drug substances, or (iii) if prohibited by applicable law or regulation.

### 5.2. Dispensing Procedures

- 5.2.1. Medco's mail order pharmacies will dispense Covered Drugs to Eligible Persons, and dispense generic drugs when authorized, in accordance with (i) applicable law and regulations in the state in which Medco's mail order pharmacy is located, and (ii) the terms of this Agreement, the Member Fund Addendum and Plan Design(s).
- 5.2.2. All matters pertaining to the dispensing of Covered Drugs or the practice of pharmacy, in general, are subject to the professional judgment of the dispensing pharmacist.
- 5.2.3. Any drug which cannot be dispensed in accordance with Medco's mail order pharmacy dispensing protocols, or which requires special record-keeping procedures, may be excluded from coverage by Medco.
- 5.2.4. If it becomes impracticable, for reasons of a force majeure or otherwise, for a specific Medco Health home delivery pharmacy to dispense prescriptions to Eligible Persons under the Program, Medco Health will use reasonable efforts to have Program prescriptions dispensed from an affiliated home delivery pharmacy, subject to applicable laws and regulations.

- 5.3. Claim Adjudication - Medco will adjudicate and pay approved claims for prescription drug benefits in accordance with Medco's TelePAID System and the applicable Plan Design. Should a Participating Member Fund determine that a previously disapproved claim should be approved, and so direct Medco, adjudication of the claim will be accomplished promptly by Medco. Union Labor Life on behalf of a Participating Member Fund will pay Medco for claims adjudicated through the TelePAID System, pursuant to Schedule A, Section 2. Medco will promptly refer to a Participating Member Fund all non-routine inquiries by insurance departments, attorneys, claimants, or other persons following the denial of any claims.

- 5.4. Pricing - The Program Pricing Terms applicable to the Mail Order Pharmacy Program are set forth in Schedule A, in addition to the Total Rebates and Guaranteed Rebates set forth in Section 6 of this Agreement.

## 6. FORMULARY

Effective January 1, 2003, NLAHCC will be a participating plan sponsor in Medco's Preferred Prescriptions® Formulary as set forth below for the term of this Agreement. Each Participating Member Fund through Union Labor Life will provide Medco with advance notice of each Group that will participate in the Preferred Prescriptions Formulary.

- 6.1. Formulary - The Preferred Prescriptions® Formulary is a prescription drug formulary administered by Medco which lists FDA approved drugs that have been evaluated for inclusion on the Preferred Prescriptions® Formulary. The drugs included on the Preferred Prescriptions® Formulary will be modified by Medco from time to time as a result of factors including, but not limited to, medical appropriateness, manufacturer rebate arrangements and patent expirations. Medco will implement Medco's formulary management programs, which may include cost containment initiatives, communications with Eligible Persons, Participating Pharmacies and/or physicians (including communications regarding generic substitution programs), and financial incentives to Participating Pharmacies for their participation. Compliance with the Preferred Prescriptions Formulary and Medco's Formulary management program will result in the Formulary Rebate Payment as set forth below. Medco reserves the right to modify or replace the Preferred Prescriptions® Formulary (including any modification or replacement, the "Formulary") and formulary compliance methods and cost containment initiatives consistent with good pharmacy practice. The NLAHCC and each Participating Member Fund agrees that Medco will be the exclusive formulary administrator for the NLAHCC and each Participating Member Fund's prescription drug benefit programs during the term of the Agreement. The NLAHCC and each Participating Member Fund is authorized to use the Formulary only for its own Eligible Persons and only as long as the Program is in effect and administered by Medco.

- 6.2. Formulary Rebates - Medco's contracts with pharmaceutical manufacturers provide Medco with rebates and fees for prescription drugs dispensed through Medco's mail order pharmacies and Medco's retail network pharmacies, as well as discounts for prescription drugs purchased and dispensed from Medco's mail order pharmacies. These contracts typically provide for two types of rebates:

- (1) rebates which are generally based on inclusion of the pharmaceutical manufacturer's products on clients' formularies and these products not being subject to restrictions that are not applicable to competing branded products are called "Formulary Rebates;" and
- (2) performance based rebates, which are typically based on various factors, including the utilization of certain drugs within their respective therapeutic categories for Medco's aggregate book of business.

Rebates are predominantly equal to a percentage of the aggregate dollar value of a particular drug that Medco dispensed, based on the manufacturer's published wholesale acquisition cost for that drug. Rebates are typically invoiced to the manufacturer and paid to Medco on a quarterly basis. Although most rebates are payable on a product basis, some manufacturers have agreed to pay rebates only if all of the specified products of the manufacturer are included on that client's formulary. Medco also receives certain fees from manufacturers for various commitments, services, and programs, which amounted to approximately \$200 million in the last reported fiscal year. Rebates and fees other than Formulary Rebates, excluding (i) mail order purchase discounts, and (ii) payments or fees from certain manufacturers that offset drug-specific dispensing, shipping, and handling and other operational costs associated with Specialty Drugs dispensed by Medco,

will be deemed "Additional Rebates and Fees" under this Agreement. Formulary Rebates and Additional Rebates and Fees will be jointly referred to as "Total Rebates."

Medco's annual reported revenues exceed \$30 billion. Medco discloses rebates, rebate percentages, and fees from manufacturers in its quarterly and annual public financial filings and will also disclose these amounts quarterly to NLAHCC as part of its policy of transparency. NLAHCC may request a cost and savings analysis regarding the interchange program; the interchange returns policy; and formulary additions, deletions, and rebates.

- 6.3. **Total Rebates** - Medco will provide the NLAHCC Participating Member Funds in aggregate with the greater of (i) 60% of the Total Rebates received by Medco based on the dispensing of each manufacturer's formulary drugs under all Participating Member Fund's Program, or (ii) the Guaranteed Rebates (as defined below). Total Rebates will be credited against future billings to the Participating Member Funds under the Program one hundred eighty (180) days after the end of each calendar quarter. Rebates due Participating Member Funds under this Agreement that are received by Medco within eighteen (18) months after termination or expiration of this Agreement will be paid to the Participating Member Funds. Rebates received thereafter will be retained by Medco.
- 6.4. The Total Rebates due to the Participating Member Funds shall be further reduced by an amount equal to 10% of such Total Rebates as a Participating Member Fund access fee, which amount shall be paid by Medco through Union Labor Life from Total Rebates as follows: 5% to NLAHCC and 5% to the Coalition to which the Participating Member Fund belongs.
- 6.5. **Guaranteed Rebates** - After each Contract Year during the Initial Term, Medco will calculate Total Rebates during such Contract Year for all Participating Member Funds. Provided NLAHCC and the Participating Member Funds comply fully with the Formulary and with the Formulary management programs implemented by Medco, if the percentage share of Total Rebates for any Contract Year during the Initial Term for all Participating Member Funds participating in the Formulary are less than the sum of (i) \$2.45 times the total number of prescriptions billed and paid for under NLAHCC's Retail Pharmacy Program during such Contract Year for all Participating Member Funds, plus (ii) \$9.30 times the total number of prescriptions billed and paid for under NLAHCC's Mail Order Pharmacy Program during the same Contract Year for all Participating Member Funds (collectively the "Guaranteed Rebates"), Medco will credit such difference against future billings to the Participating Member Funds under the program one hundred eighty (180) days after the end of each Contract Year.
- 6.6. Any lines of any Participating Member Fund's business, or any Group of Eligible Persons, for which any Participating Member Fund funds less than 50% of the costs of Covered Drugs under the Plan Design will not be entitled to Formulary Rebate Payment. Calculations and payments under Section 6.3 will not include prescriptions dispensed for any such lines of business or Groups.
- 6.7. If a government action, change in law or regulation, change in the interpretation of law or regulation, or action by any drug manufacturer or by the NLAHCC, Union Labor Life or any Participating Member Fund has a material adverse effect on the availability of Formulary Rebate Payments, Medco may modify the Program Pricing Terms.

## 7. BILLING/PAYMENT

Each Participating Member Fund will be responsible to pay Medco through Union Labor Life for services provided by Medco to Eligible Persons in such Participating Member Fund in accordance with the terms in Schedules A, B, C and D.



## 8. RECORDS

- 8.1. Medco will maintain all claims records relating to services performed under this Agreement as required by applicable law. Such claims records will be in their original form, on microfilm, microfiche, or other form determined by Medco. The NLAHCC's collective claims records may be audited, based on statistical sampling, or up to eight individual NLAHCC Participating Member Funds may perform individual claims audits, either directly or by a representative approved by Medco, subject to execution of a confidentiality agreement, for a maximum period of twenty-four (24) months prior to the agreed upon audit date, subject to applicable confidentiality provisions and legal requirements. Any audit by the NLAHCC or Participating Member Funds may be conducted once annually upon adequate prior written notice, and during regular business hours. Subject to Section 9.1 Medco may retain copies of such claims records for its own use. Medco's costs for any additional audits beyond the one collective audit or eight individual audits will be paid by NLAHCC or the Participating Member Funds.
- 8.2. Medco's agreements with pharmaceutical manufacturers are subject to confidentiality agreements. The NLAHCC will be entitled to one collective audit, based on statistical sampling, under this Section 1.2 on behalf of all NLAHCC member funds, or up to eight individual NLAHCC Participating Member Funds may perform individual manufacturer agreement audits. Any audit of Medco's agreements with pharmaceutical manufacturers will be conducted by (a) a Big 4 public accounting firm approved by Medco whose audit department is a separate stand alone function of its business, or (b) a national CPA firm approved by Medco whose audit department is a separate stand alone function of its business. The organization that will be performing the audit must carry insurance for professional malpractice of at least \$2,000,000. The audit will include only those portions of such pharmaceutical manufacturer agreements as necessary to determine Medco's compliance with Section 6 above in respect to Total Rebates. The audit will be conducted once annually, during normal business hours, at Medco's offices as scheduled by agreement of the parties, but not sooner than ninety (90) days after execution of Medco's confidentiality agreement. Medco's costs for any additional audits beyond the one collective audit or eight individual audits will be paid by NLAHCC or the Participating Member Funds.
- 8.3. Any auditor performing an audit under Section 0 or 8.2 above will be required to warrant and represent that it is not providing services to any person, company, or other entity (such as plan sponsors and law firms) in connection with any lawsuit, investigation, or other proceeding that is currently pending or contemplated against Medco. Such services include, but are not limited to (a) examining pharmacy claims or any other data, documents, information or materials or (b) providing advice, analysis, assessments, and/or opinions as a disclosed or undisclosed expert or consultant (collectively "Litigation Services"), in connection with any lawsuit, investigation, or other proceeding pending or contemplated against Medco. The auditor must agree that, for a period of one (1) year after completion of the audit, it will not provide Litigation Services in any lawsuit, investigation, or other proceeding brought against Medco, except for Litigation Services to the NLAHCC in any proceeding against Medco.
- 8.4. Each Participating Member Fund will furnish its most recent audited financial statement to Medco Health prior to the Effective Date of this Agreement and thereafter will furnish its annual audited financial statement to Medco Health within ninety (90) days after the end of each fiscal year of each Participating Member Fund that this Agreement is in effect.

## 9. CONFIDENTIAL INFORMATION

- 9.1. The Confidential Information of a party (the "disclosing party") which is disclosed to the other party (the "receiving party") will be held by the receiving party in strictest confidence at all times and will not be used by the receiving party (or its affiliates, employees, officers, directors or limited liability company managers and agents ("Representatives")) for any purpose not previously authorized by the disclosing party, except as necessary for Medco to perform the

services under this Agreement. The Confidential Information of the disclosing party will not be disclosed or divulged by the receiving party to anyone, except as required by law or regulation, or with the prior written permission of the disclosing party and on the condition that the party to whom the Confidential Information is disclosed agrees in writing in advance to be bound by these terms and conditions. The receiving party may disclose the Confidential Information to those of its employees or advisors who need to review the Confidential Information for the purposes authorized by the disclosing party but only after the receiving party has informed them of the confidential nature of the Confidential Information and directs them to treat the Confidential Information in accordance with the terms of this Agreement. The disclosing party retains all right, title and interest in and to its Confidential Information.

The term "Confidential Information" includes, but is not limited to, any information of either the receiving or disclosing party (whether oral, written, visual or fixed in any tangible medium of expression), relating to either party's services, operations, systems, programs, inventions, techniques, suppliers, customers and prospective customers, contractors, cost and pricing data, trade secrets, know-how, processes, plans, reports, designs and any other information of or relating to either party's business, including its therapeutic, disease management, and health education programs, but does not include information which (a) was known to the receiving party before it was disclosed to the receiving party by the disclosing party, (b) was or becomes available to the receiving party from a source other than the disclosing party, provided such fact is evidenced in writing and the source is not bound by a confidentiality obligation to the disclosing party, or (c) is developed by the receiving party independently of the disclosing party's Confidential Information, provided that such fact can be documented. Each party will also keep the terms of this Agreement confidential as Confidential Information, except as required by law or regulation.

If the receiving party is requested or required (by oral questions, interrogatories, requests for information or documents, subpoena, civil investigative demand, any informal or formal investigation by any government or governmental agency or authority, law or regulation, or otherwise) to disclose any of the Confidential Information, the receiving party will notify the disclosing party promptly in writing so that the disclosing party may seek a protective order or other appropriate remedy or, in its sole discretion, waive compliance with the terms of this Agreement. The receiving party agrees not to oppose any action by the disclosing party to obtain a protective order or other appropriate remedy. If no such protective order or other remedy is obtained, or the disclosing party waives compliance with the terms of this Agreement, the receiving party will furnish only that portion of the Confidential Information which it is advised by counsel is legally required and will exercise its reasonable best efforts to obtain reliable assurance that confidential treatment will be accorded the Confidential Information.

- 9.2. NLAHCC and Medco may not utilize the service marks, trademarks, or trade names of any other party to this Agreement, or any service marks, trademarks, or trade names so similar as likely to cause confusion, without express written approval of such other party. The programs implemented by Medco will remain the sole property of Medco and will only be used by NLAHCC in connection with the Program and so long as Medco administers the Program.
- 9.3. Medco, NLAHCC and each Participating Member Fund will comply with all applicable laws and regulations regarding patient confidentiality. Medco will not furnish any patient identifiable or Participating Member Fund identifiable data or information to any third party without the written consent of that Participating Member Fund, except as reasonably necessary to implement and operate the Program and fulfill its obligations pursuant to this Agreement or as required by applicable law. The restrictions set forth in this Section 9 will not apply to claims data or information which is not identifiable on a Participating Member Fund or patient basis.



## 10. TERM OF AGREEMENT

- 10.1. This Agreement will remain in effect for an initial term of three (3) years (the "Initial Term") and thereafter will automatically renew for successive one (1) year terms unless either party gives written notice, at least one hundred eighty (180) days prior to the end of any such term, to the other party of its intent to terminate this Agreement as of the end of the then current term. Notwithstanding the termination of this Agreement or Member Fund Addendum, Medco agrees to continue to render services hereunder and each Participating Member Fund through Union Labor Life agrees to pay for services of Medco in accordance with the terms of this Agreement and the Member Fund Addendum for any claims incurred for prescription drug benefits by Eligible Persons while this Agreement and the Member Fund Addendum was in force.
- 10.2. In the event of a material breach of this Agreement or Member Fund Addendum, the party alleging such breach will give written notice thereof to the other parties. If such breach is not cured within sixty (60) days of receipt of such notice, the non-breaching party may terminate this Agreement or Member Fund Addendum upon written notice to the other party.
- 10.3. The NLAHCC and each Participating Member Fund acknowledge that in the event of expiration or termination, inability to agree on the terms of that agreement to reflect the terms of this Agreement, of Medco's agreement with Union Labor Life that the Agreement between Medco and the NLAHCC and each Participating Member Fund shall survive any such termination and be amended by Medco and the NLAHCC and each Participating Member Fund to address the obligations of and the services that Union Labor Life had been providing to the NLAHCC and its Participating Member Funds pursuant to this terms of this Agreement.

## 11. FORCE MAJEURE

Neither Medco, a Participating Member Fund, nor NLAHCC will be deemed to have breached this Agreement or Member Fund Addendum or be held liable for any failure or delay in the performance of all or any portion of its obligations under this Agreement or Member Fund Addendum if prevented from doing so by a cause or causes beyond its control. Without limiting the generality of the foregoing, such causes include acts of God or the public enemy, fires, floods, storms, earthquakes, riots, strikes, boycotts, lock-outs, acts of terrorism, acts of war or war-operations, restraints of government, power or communications line failure or other circumstances beyond such party's control, or by reason of the judgment, ruling or order of any court or agency of competent jurisdiction, or change of law or regulation (or change in the interpretation thereof) subsequent to the execution of this Agreement or Member Fund Addendum.

## 12. INDEMNIFICATION/LIMITATION OF LIABILITY

- 12.1. Medco will indemnify and hold NLAHCC, its officers, directors and employees (each an "Indemnified Party") harmless from claims or causes of action asserted against an Indemnified Party arising from services rendered by Medco pursuant to this Agreement to the extent the claim or cause of action arises out of Medco's negligence or willful misconduct, provided that (a) NLAHCC has given reasonable notice to Medco of the claim or cause of action, and (b) no Indemnified Party has, by act or failure to act, compromised Medco's position with respect to the resolution or defense of the claim or cause of action.
- 12.2. NLAHCC will indemnify and hold Medco, its subsidiaries and affiliates, and their respective officers, directors and employees (each an "Indemnified Party") harmless from claims or causes of action asserted against an Indemnified Party arising from (i) negligence or willful misconduct of NLAHCC, including without limitation, the disclosure and/or use of Program data or information provided by Medco to NLAHCC, or (ii) the provision of patient identifiable data by Medco or its subsidiaries to NLAHCC or NLAHCC's designees, provided that (a) the Indemnified Party has given reasonable notice to NLAHCC of the claim or cause of action, and (b) no Indemnified Party

has, by act or failure to act, compromised NLAHCC's position with respect to the resolution or defense of the claim or cause of action.

- 12.3. Medco will maintain, during the term of this Agreement, liability coverage with limits not less than \$1,000,000 per occurrence and in the aggregate per policy year, with excess liability coverage in an amount not less than \$5,000,000 per policy year. Evidence thereof will be furnished to NLAHCC upon request.
- 12.4. Except as provided in Section 12.1 above, Medco or any affiliated company, or their directors, officers or employees, will not be responsible for any claim, loss or damage sustained as a result of the provision of or failure to provide pharmaceutical goods or services or any other action or failure to act by any retail pharmacy, pharmaceutical manufacturer or other pharmaceutical providers pursuant to this Agreement.
- 12.5. The liability of Medco to NLAHCC for any negligent or willful misconduct by Medco in the performance of its obligations hereunder will be limited to the liability insurance amounts set forth in Section 12.3.
- 12.6. Medco, NLAHCC or each Participating Member Fund will not be liable to each other for incidental, consequential or exemplary damages.

### 13. EXCLUSIVITY

Medco will be the exclusive provider and administrator of PBM Services to NLAHCC and each Participating Member Fund while this Agreement and Member Fund Addendum are in effect. Nothing contained herein, however, will prohibit Medco or any affiliated entity from providing or administering PBM Services and related programs and services to any other entity while this Agreement or Member Fund Addendum are in effect.

### 14. GENERAL

- 14.1. Independent Contractor - The relationship between Medco and NLAHCC will solely be that of independent contractors engaged in the operation of their own respective businesses.
- 14.2. Assignment - This Agreement may not be assigned by any party without the written approval of the other parties provided, however, that services to be performed by Medco hereunder may be performed by its subsidiaries, affiliates, divisions and/or designees. The duties and obligations of the parties will be binding upon, and inure to the benefit of, successors, assigns, or merged or consolidated entities of the parties.
- 14.3. No Third-Party Beneficiary - This Agreement has been entered into solely for the benefit of NLAHCC and Medco, and is not intended to create any legal, equitable, or beneficial interest in any third party or to vest in any third party any interest as to enforcement or performance.
- 14.4. Notices - All notices required under this Agreement will be in writing and sent by certified mail, return receipt requested, hand delivery or overnight delivery by a nationally recognized service addressed as follows:

If to NLAHCC: Health Care Payers Coalition of New Jersey  
91 Fieldcrest Avenue  
Raritan Plaza II, P. O. Box 6858  
Edison, NJ 08818  
Attention: Mr. Edward M. Geisler

If to Medco: Medco Health Solutions, Inc.  
100 Parsons Pond Drive  
Franklin Lakes, NJ 07417  
Attention: Thomas M. Moriarty  
Vice President and Managing Counsel  
Commercial Transactions

To each Participating  
Member Fund: As set forth in each Member Fund Addendum

- 14.5. **Amendments** - This Agreement or Member Fund Addendum may be amended only in writing when signed by a duly authorized representative of each party.
- 14.6. **Financial Responsibility** - If Medco has reasonable grounds to believe that a Participating Member Fund may not meet its payment obligations under this Agreement as they become due, Medco may request information and/or reasonable assurances (including a deposit) from such Participating Member Fund as to its financial responsibility. If the information or assurances are not furnished to Medco within five (5) days, or are not satisfactory in Medco's reasonable judgment, Medco may immediately terminate the specific Participating Member Fund.
- 14.7. **Plan Design** - The Program Pricing Terms set forth in this Agreement or Member Fund Addendum are based upon the Plan Designs, Minimum Enrollment and Program specifications agreed to between the parties as reflected in this Agreement or Member Fund Addendum and as otherwise hereafter agreed to by the parties in writing. The Program Pricing Terms are also based upon each Participating Member Fund funding 50% or greater of the costs of Covered Drugs for its Eligible Persons. Any modification of the Plan Design or Program specifications, failure to maintain Minimum Enrollment, or inclusion of Eligible Persons or Groups with Covered Drugs funded less than 50% by any Participating Member Fund, may result in a retroactive modification by Medco of the Program Pricing Terms. Each Participating Member Fund will provide Eligible Persons with at least thirty (30) days prior notice of approved Plan Design changes.
- 14.8. **Interpretation of Plan** - NLAHCC will not name or represent that Medco, is, and Medco will not be, a Plan Administrator or a fiduciary of NLAHCC's prescription drug benefit plan (the "Plan"), as those terms are used in the Employee Retirement Income Security Act ("ERISA"), 29 U.S.C. §§ 1001 et seq., and the regulations promulgated under ERISA. NLAHCC will have complete discretionary, binding and final authority to construe the terms of the Plan, to interpret ambiguous Plan language, to make factual determinations regarding the payment of claims or provisions of benefits, to review denied claims and to resolve complaints by Eligible Persons.
- 14.9. **Tax** - Any applicable sales, use, or other similarly assessed and administered tax imposed on items dispensed, or services provided hereunder, will be the sole responsibility of NLAHCC or Participating Member Fund. If Medco is legally obligated to collect and remit sales, use, or other similarly assessed and administered tax in a particular jurisdiction, the tax will be reflected on the applicable invoice or subsequently invoiced at such time as Medco becomes aware of such obligation.
- 14.10. **Governing Law** - This Agreement will be construed and governed in accordance with the laws of the State of New Jersey. However, all matters relating to the Mail Order Pharmacy Program operations of Medco will be governed by the laws of the state in which Medco's mail order pharmacy is located.
- 14.11. **Enforceability** - The invalidity or unenforceability of any of the terms or provisions hereof will not affect the validity or enforceability of any other term or provision.
- 14.12. **Section Headings** - Section headings are inserted for convenience only and will not be used in any way to construe the terms of this Agreement.

- 14.13. Waiver - The waiver of any breach or violation of any term or provision hereof will not constitute a waiver of any subsequent breach or violation of the same or any other term or provision.
- 14.14. Approvals - Whenever approval of any party is required under this Agreement, such approval will not be unreasonably withheld.
- 14.15. Organization - Each party is duly organized, validly existing and in good standing, and has the power to own its property and to carry on its business as now being conducted by it.
- 14.16. Authorization - The execution and delivery of this Agreement and the consummation of the transactions contemplated herein on its part, has been duly authorized by all necessary action by each party.
- 14.17. No Conflict of Interest or Other Restrictions - No party has a conflict of interest which would impact its ability to perform fairly its obligations under this Agreement, and no party is subject to any restrictions, contractual or otherwise, which prevent or would prevent it from entering into this Agreement or carrying out its obligations hereunder.
- 14.18. No Violation - Neither the execution and delivery of this Agreement nor the consummation of the transactions contemplated hereby will be a violation or default of any term or provision of the party's governance documents (e.g., its certificate of incorporation or bylaws or operating agreement) or of any material contract, commitment, indenture, or other agreement or restriction to which it is a party or by which it is bound.
- 14.19. Binding Effect - This Agreement has been duly executed and delivered by each party, and is a valid and binding obligation of each party, enforceable against such party in accordance with its terms, except to the extent that the enforceability thereof may be limited by applicable bankruptcy, insolvency, reorganization, moratorium or similar laws affecting creditors' rights generally and general principles of equity.
- 14.20. Original Agreement/Counterparts - The parties will execute two identical originals of this Agreement. Each party will retain one of the originals. This Agreement may be executed in one or more counterparts, any one of which need not contain the signatures of more than one party, but all counterparts taken together will constitute one instrument.
- 14.21. Public Announcement - Except as required by law or regulation, neither party will make any public announcement nor issue any press release relating to this Agreement without the written consent of the other party. This provision does not restrict either party from submitting necessary or appropriate filings with the SEC.
- 14.22. Dispute Resolution - Except for those matters subject to emergent or injunctive relief, in the event that any dispute relating to this Agreement arises between NLAHCC or Participating Member Fund and Medco, either party may, by written notice, demand a meeting regarding the dispute, to be attended by executive officers of each party, who will attempt in good faith to resolve the dispute. If the dispute cannot be resolved through executive negotiations within thirty (30) business days after the date of the initial notice, each party will retain all rights to bring an action regarding such matter in accordance with law.
- 14.23. Entire Agreement - This Agreement, together with the Schedules and Member Fund Addenda hereto, embodies the entire understanding of the parties in relation to the subject matter hereof, supersedes any prior agreement among the parties in relation to the subject matter hereof, and no other agreement, understanding, or representation, verbal or otherwise, relative to the subject matter hereof exists among the parties at the time of execution of this Agreement.
- 14.24. Survival - The provisions of Sections 7, 9, 12 and the last sentence of 10.1 will survive the termination of this Agreement.

14.25. Most Favored Pricing - Medco will extend a "most favored pricing" ("MFP") provision to NLAHCC. The aggregate pricing terms provided by Medco to NLAHCC for all NLAHCC Member Funds written through the NLAHCC, or by Medco or Systemed directly, will be no less favorable than the aggregate pricing terms provided by Medco or Systemed to any other health and welfare funds, or benefit and welfare coalitions, of the same or smaller size that has similar programs, services, plan designs and mail utilization ("Comparison Account"). The value of all rebates paid under Section 6.4 is included in the aggregate calculation of Medco's pricing to the NLAHCC. This provision is subject to the following conditions:

14.25.1. All existing Medco PBM clients are excluded from being Comparison Accounts and cannot be used as a basis for this MFP provision, with the exception of VEBA and GOLD COAST/SCEET which will become Comparison Accounts when they become Participating Member Funds under this Agreement.

14.25.2. Groups that are, or become, Medco or Systemed clients on or after July 1, 2005 that subsequently become NLAHCC Member Funds would also be excluded from being Comparison Accounts.

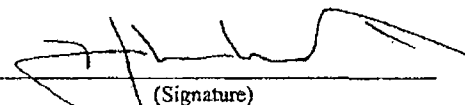
14.25.3. It is the responsibility of the NLAHCC to provide an accurate and up to date listing of NLAHCC Member Funds to Medco.

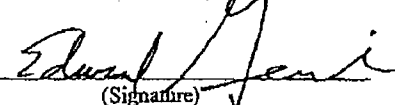
14.26. Compensation Disclosure - The only compensation that Medco shall receive pursuant to the terms of this Agreement with the NLAHCC and its Member Funds shall be the fees described herein, the Total Rebates as defined herein, fees received from retail pharmacies for access to Medco's TelePAID system, a fee in an amount agreed to by the parties for any additional services authorized by the NLAHCC and its Member Funds, and any fees or payments received from third parties for aggregated (non-NLAHCC, non-Member Fund, or non-Eligible Person identification basis) claims data pursuant to Section 9.3. All other amounts received directly or indirectly by Medco, no matter how described or characterized, from third parties, whether by cash, by a credit, or by in kind contribution, shall be disclosed and forwarded to the NLAHCC and its Member Funds except as described herein.

IN WITNESS WHEREOF, the parties have executed this Agreement on the date indicated below.

MEDCO HEALTH SOLUTIONS,  
INC.

THE NATIONAL LABOR  
ALLIANCE OF HEALTH  
CARE COALITIONS, INC.

BY:   
(Signature)

BY:   
(Signature)

NAME: Thomas M. Moriarty

NAME: Edward Geisler  
(type or print name)

Vice President and Managing Counsel  
TITLE: Commercial Transactions

PRESIDENT  
TITLE: President

DATE: 7/15/05

DATE: 6/15/05

55825.1 (06/09/05) gsm  
(Original 26456.13 - 2/19/03)

55825.1 (06/03/05)

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CARP-00072

## SCHEDULE A

### PROGRAM PRICING TERMS

Effective February 7, 2003, each Participating Member Fund through Union Labor Life will pay Medco for services provided by Medco under the Program as follows:

#### 1. RETAIL PHARMACY PROGRAM CLAIMS

Each Participating Member Fund through Union Labor Life will pay Medco Health for Covered Drugs dispensed and submitted by Participating Pharmacies in an amount equal to the lowest of (i) the pharmacy's usual and customary price, as submitted ("U&C") plus applicable taxes, (ii) the maximum allowable cost ("MAC"), where applicable, plus the Dispensing Fee set forth below, plus applicable taxes, or (iii) AWP minus (-) 15.5%, plus the Dispensing Fee set forth below, plus applicable taxes. Payment by each Participating Member Fund through Union Labor Life is subject to the applicable Copayment/Coinsurance or other coverage features set forth in the Plan Design designated by each Participating Member Fund through Union Labor Life under the Retail Pharmacy Program.

- 1.1 Dispensing Fee - The Dispensing Fee per prescription or authorized refill will be \$1.75 for Brand Name Drugs without MAC pricing, and \$1.75 for Generic Drugs and Brand Name Drugs that are billed at MAC, consistent with the applicable Plan Design.
- 1.2 Copayment/Coinsurance - The Copayment/Coinsurance amount for each prescription or authorized refill will be as designated in the applicable Plan Design(s).
- 1.3 Minimum Charge at Retail - Each Participating Member Fund through Union Labor Life agrees there may be a minimum charge at retail for a Covered Drug of the lower of (a) the U&C or (b) the applicable Copayment. For prescriptions or refills where this minimum charge applies, there will be no charge/credit to such Participating Member Fund under this Section 1.
- 1.4 Direct Claims - The reimbursement terms applicable to direct reimbursement claims submitted by Eligible Persons under the Retail Pharmacy Program will be the same as the terms set forth in this Section 1, unless otherwise provided in writing by the Participating Member Fund to Medco.
- 1.5 Generic Drug Guarantee
  - 1.5.1 Medco guarantees that, as a result of the Medco network management programs, the average effective AWP discount for Generic Drugs, as billed to Participating Member Funds, in aggregate, dispensed and submitted by Participating Pharmacies, in the aggregate, for each Contract Year during the Initial Term will be minus (-) 50% (the "Guaranteed Generic Discount"). In the event of a material Plan Design modification, an increase or decrease in the total number of Participating Pharmacies by greater than five (5) percent, or a change in ownership of five (5) percent or more of Participating Pharmacies, Medco may modify the Guaranteed Generic Discount on an equitable basis.
  - 1.5.2 Within one hundred eighty (180) days after the end of each Contract Year during the Initial Term, Medco will calculate and report the actual average Generic Drug AWP discount achieved for all Generic Drugs as billed to Participating Member Funds, in aggregate, dispensed, and submitted by Participating Pharmacies, in the aggregate, for such Contract Year (the "Actual Generic Discount"). If the Actual Generic Discount for any such Contract Year is less than the Guaranteed Generic Discount, Medco will credit the full dollar amount of such shortfall against future billings to the Participating Member Funds under the Program.



- 1.5.3 So long as the guarantee set forth in this Section 1.5 is in effect, Medco will have no separate liability for Generic Drugs under the Retail Pharmacy Program pricing set forth in Section 1 of this Schedule A.

## 2. MAIL ORDER PHARMACY PROGRAM CLAIMS

Each Participating Member Fund through Union Labor Life will pay Medco for Covered Drugs dispensed by Medco under the Mail Order Pharmacy Program in an amount equal to an Ingredient Cost plus Dispensing Fee for each Covered Drug dispensed, less the applicable Copayment/Coinsurance amount, as such terms are defined below:

- 2.1 Ingredient Cost - The Ingredient Cost is AWP minus (-) 23% for Brand Name Drugs and AWP minus (-) 55% for Generic Drugs.
- 2.2 Dispensing Fee - The Dispensing Fee per prescription or authorized refill is \$0.00. Dispensing Fees are inclusive of postage. If postage rates (i.e., U.S. mail and/or applicable commercial courier services) increase during the term of this Agreement, the Dispensing Fee will be increased to reflect such increase(s).
- 2.3 Copayment/Coinsurance - The Copayment/Coinsurance amount for each prescription or refill dispensed by Medco under the Home Delivery Pharmacy Program shall be as designated for each Group of each Participating Member Fund in the applicable Plan Design(s). If the amount of the applicable Copayment/Coinsurance paid by an Eligible Person for a prescription or refill dispensed by Medco exceeds the Ingredient Cost (as defined in 2.1 above) plus Dispensing Fee (as defined in Section 2.2 above) plus any applicable sales tax, then Medco shall return to the Eligible Person an amount equal to the Copayment/Coinsurance amount, less the sum of the applicable Ingredient Cost plus Dispensing Fee plus any applicable sales tax, for the prescription or refill. Eligible Persons must pay the applicable Copayment or Coinsurance amount to Medco for each prescription or authorized refill under the Home Delivery Pharmacy Program. Medco may suspend Home Delivery Pharmacy Program services to an Eligible Person who is in default of any Copayment or Coinsurance amount due Medco. The applicable Participating Member Fund will be responsible for any unpaid Eligible Person Copayment or Coinsurance amounts if payment has not been received from the Eligible Person of that Participating Member Fund within one hundred twenty (120) days of dispensing. The Participating Member Fund will be billed following the one hundred twenty (120) day collection period, with payment due in accordance with the payment terms set forth in Section 7 of this Agreement and Section 2.2 of the applicable Member Fund Agreement.

## 3. SPECIALTY DRUG CLAIMS

Notwithstanding anything to the contrary in Section 2 above and elsewhere in the Agreement, effective July 1, 2005, NLAHCC will pay Medco for those Covered Drugs designated as Specialty Drugs in Schedule B under the Mail Order Pharmacy Program on a separate ingredient cost basis (provided in Schedule B) plus applicable Dispensing Fee (provided in Schedule B), subject to the Copayment/Coinsurance in the applicable Plan Design. Under the Retail Pharmacy Program, NLAHCC will pay Medco for the Specialty Drugs in Schedule B according to the pricing set forth in Section 1 of Schedule A. Specialty Drugs may be provided by Medco or other third-party specialty pharmacy that has a written arrangement with Medco. Medco may add or delete products, or modify pricing terms, in Schedule B on written notice to NLAHCC. Specialty Drugs are excluded from calculations, guarantees, credits, and payments regarding Total Rebates under the Mail Order Pharmacy Program and the Retail Pharmacy Program set forth in this Agreement.

Services for Specialty Drugs under the Mail Order Pharmacy Program consist of:

- Clinical support that provides, according to Medco's procedures:
  - Eligible Person counseling
  - Care management, including information and support directly to the Eligible Person
  - Coordination of care with the Eligible Persons case manager and/or home care agency
- Specialty Drug educational materials and product information
  - Standard communications notifying Eligible Persons of changes in plan coverage
  - Personalized mailings and outbound phone calls by Medco Special Care Pharmacy to Eligible Persons purchasing, at retail pharmacies, Specialty Drugs that are clinically appropriate for maintenance use
- Toll-free telephone line for Eligible Persons using Specialty Drugs
- Express delivery to physician's office or Eligible Person's home
  - Standard two (2) day delivery
  - Overnight delivery as physician required (excluding Sundays)
- Logistics coordination of delivery to Eligible Person's home or physician's office
- Analysis of integrated pharmacy and medical claims databases to identify utilizers, if applicable and agreed upon
- Ancillary supplies provided with each injectable medication
- Drug Utilization Review applied to specialty pharmacy related prescription claims and, when available from Medco, medical claims
- Enhanced Physician services, consisting of communication materials, forms and informational hotline

Additional communications to Eligible Persons or physicians beyond these listed above will be quoted upon request.

#### 4. ADMINISTRATIVE FEES

- 4.1 Each Participating Member Fund through Union Labor Life will pay to Medco a Base Administrative Fee in the amount of \$0.00 per transaction processed by Medco under the Retail Pharmacy Program or Mail Order Pharmacy Program for the following Base Administrative Services, as applicable:

##### Claim Adjudication

- Administration of each Participating Member Fund through Union Labor Life Plan Design
- In-network claims adjudication via TelePAID® on-line claims adjudication system
- Primary Coordination of Benefits (COB) (when flagged on eligibility records)
- Twelve (12) months on-line claims history retention (for use in claims processing)
- Processing associated with Mail Order Pharmacy Program prescriptions

##### Member Communication Materials

- Medco Welcome Package for new designated Eligible Persons, consisting of:
  - Announcement letter (not to exceed one page)
  - Medco descriptive brochure (not to exceed eight pages)
  - Pre-addressed mail order order form/envelope
  - Patient health profile questionnaire
  - One Medco Identification Card per Primary Eligible Participant (two per family)



- Information on access to major Participating Pharmacy network chains
- Other available standard Medco materials, consisting of:
  - Direct reimbursement claim form (also available via [www.medco.com](http://www.medco.com))
  - Coordination of Benefits (COB) claim form
- TDD-TTY services for hearing impaired to access Member Service Department

#### Drug Utilization Review/Clinical/Formulary Programs

- Integrated Concurrent Drug Utilization Review (DUR) via TelePAID®, including plan management alerts and clinical alerts

#### Reporting

- Medco's Prescription Drug Plan Report Package

#### Retail Pharmacy Network

- Establish, maintain, credential and contract an adequate panel of Participating Pharmacies
- Development and distribution of communication materials to Participating Pharmacies regarding the Program
- Toll-free access to Help Desk for eligibility/claims processing assistance
- Toll-free access for Participating Pharmacies to obtain DUR assistance
- Monitor Participating Pharmacy performance and compliance, including generic substitution rates, formulary program conformance, and DUR intervention conformance through Retail Network Management initiatives and reporting
- Toll-free telephone access to voice response unit for location of Participating Pharmacies in zip code area
- Medco Pharmacy Audit Program

#### Member Service

- Toll-free telephone access to Member Service for the Program for use by Eligible Persons, NLAHCC benefits personnel and physicians
- Gatekeeper Program
- 24 hour access to a Medco pharmacist via toll-free telephone service

#### medco.com

- Standard Medco website capabilities, including:
  - online prescription ordering and status
  - prescription pricing information
  - coverage and benefit plan information
  - health news information
  - health assessment tools and resources

- 4.2 Each Participating Member Fund through Union Labor Life will also pay for Additional Administrative Services requested by each Participating Member Fund and provided by Medco under the Program as follows:

#### Eligibility

- Hard copy eligibility submission

Data entry charges

**Claim Adjudication**

- Direct reimbursement (under Retail Pharmacy Program)/out-of-network claims adjudication (including check and EOB to Eligible Person) \$1.00 per claim
- Coordination of Benefits (COB)
  - Secondary Coordination of Benefits
    - Eligible Person-submitted paper claim \$2.50 per claim
    - Retail Pharmacy-submitted electronic claim \$1.00 per claim
  - Medicare Part B Recovery (Mail Order Pharmacy Program only) \$25.00 per claim submitted to Medicare for processing
  - Adjudication of government reimbursement claims (unless responsibility is otherwise assigned by NLAHCC) \$3.00 per paid claim
- On-line claims history retention (for use in claims processing) in excess of twelve (12) months \$0.05 per claim

**Drug Utilization Review/Clinical/Formulary Programs**

- Set-up and load of historical records from prior vendor, supplied in Medco format \$0.07 per claim<sup>1</sup>
- Medco's Coverage Authorization Program, consisting of: prior authorization, step therapy, quantity duration/ dose duration, quantity per dispensing event capabilities, and dose optimization (coverage option) \$40.00 per case
- Pre-Notification Eligible Person Mail Campaign Quoted upon request
- Authorization renewal Eligible Person notification Quoted upon request
- High Utilization Management Program (Level II - Intervention) \$0.05 per claim
- Retrospective DUR \$0.10 per claim
- Customized Physician Practice Summary Program Quoted upon request
- Optimal Therapeutics<sup>SM</sup> – Medco's academic detailing program for physicians Quoted upon request
- Retail Brand to Generic Patient Education Program \$3.00 per letter

**Reviews and Appeals Management**

- Reviews and Appeals Management
  - Administrative \$15.00 per case
  - Clinical – conditions of coverage reported by physician (not associated with Coverage Management Programs) \$40.00 per case

<sup>1</sup> Fee waived for the first six months after the Effective Date if a Participating Member Fund implements Retrospective DUR at \$0.10 per claim on the Effective Date.

- Reviews and Appeals Management for Medco's Coverage Management Programs No additional charge beyond the charge for Medco's Coverage Management Program<sup>2</sup>

#### Reporting

- Ad-hoc report production, reprogramming and testing of non-standard NLAHCC requirements Quoted upon request
- Each Participating Member Fund's requests through Union Labor Life for claims data and production files for itself or its designees (pricing varies based on required turnaround time and is subject to execution of Medco's confidentiality agreement) Quoted upon request

#### Member Communication Materials

- Replacement of any Member Communication Materials or Identification Cards upon an Eligible Person's request Actual replacement cost
- Customization, re-issuance or replacement of Member Communication Materials or Identification Cards on a Group or Participating Member Fund-wide basis, if requested by each Participating Member Fund Quoted upon request
- Periodic Explanation of Benefits to Eligible Persons providing informational and cost savings messages, account summaries, and cost share per claim Quoted upon request
- Eligible Person communications describing the benefit or changes to the benefit, except for initial Welcome Package for new designated Eligible Persons Quoted upon request
- Customized, targeted Eligible Person mailings for closed/custom formulary Quoted upon request
- Retail Refill Allowance Program Member Communications Materials Quoted upon request
- Mailings direct to Eligible Persons, physicians or each Participating Member Fund's location Postage charges

Note: Charges for additional services not listed above will be determined by Medco and quoted upon request.

<sup>2</sup> Additional charges may be incurred for non-standard Participating Member Fund specific requirements, processing and/or communications.

**SCHEDULE B**  
**SPECIALTY DRUGS**

THERAPEUTIC CLASS	BRAND NAME	AWP DISCOUNT %	DISPENSING FEE*
Alpha-1 Proteinase Deficiency	ARALAST	15.00%	\$1.75
Alpha-1 Proteinase Deficiency	ZEMAIRA	15.00%	\$1.75
Anemia/Neutropenia	ARANESP	15.00%	\$1.75
Anemia/Neutropenia	EPOGEN	15.00%	\$1.75
Anemia/Neutropenia	LEUKINE	15.00%	\$1.75
Anemia/Neutropenia	NEULASTA	15.00%	\$1.75
Anemia/Neutropenia	NEUMEGA	15.00%	\$1.75
Anemia/Neutropenia	NEUPOGEN	15.00%	\$1.75
Anemia/Neutropenia	PROCRIT	15.00%	\$1.75
Anti-infective	CYTOVENE	15.00%	\$1.75
Asthma	XOLAIR	15.00%	\$1.75
Cancer	AVASTIN	15.00%	\$1.75
Cancer	ELIGARD	15.00%	\$1.75
Cancer	GLEEVEC	15.00%	\$1.75
Cancer	HERCEPTIN	15.00%	\$1.75
Cancer	IRESSA	15.00%	\$1.75
Cancer	PROLEUKIN	15.00%	\$1.75
Cancer	RITUXAN	15.00%	\$1.75
Cancer	SANDOSTATIN	15.00%	\$1.75
Cancer	TARCEVA	15.00%	\$1.75
Cancer	TEMODAR	15.00%	\$1.75
Cancer	VIDAZA	15.00%	\$1.75
Cancer	XELODA	15.00%	\$1.75
Cancer	ZOLADEX	15.00%	\$1.75
Cancer	LEUPROLIDE	17.00%	\$1.75
Cancer	LUPRON	17.00%	\$1.75
Cystic Fibrosis	PULMOZYME	16.00%	\$1.75
Cystic Fibrosis	TOBI	16.00%	\$1.75
DVT/Anticoagulation	ARIXTRA	15.00%	\$1.75
DVT/Anti-Coagulation	FRAGMIN	15.00%	\$1.75
DVT/Anti-Coagulation	INNOHEP	15.00%	\$1.75
DVT/Anti-Coagulation	LOVENOX	15.00%	\$1.75
Fabry Disease	FABRAZYME	10.00%	\$1.75
Gaucher's	CEREZYME	15.00%	\$1.75
Growth Hormone	GENOTROPIN	16.00%	\$1.75
Growth Hormone	GEREF	16.00%	\$1.75
Growth Hormone	HUMATROPE	16.00%	\$1.75
Growth Hormone	NORDITROPIN	16.00%	\$1.75
Growth Hormone	NUTROPIN	16.00%	\$1.75
Growth hormone	NUTROPIN AQ	16.00%	\$1.75
Growth hormone	NUTROPIN DEPOT	16.00%	\$1.75
Growth Hormone	PROTROPIN	16.00%	\$1.75
Growth Hormone	SAIZEN	16.00%	\$1.75
Growth Hormone	SEROSTIM	16.00%	\$1.75
Growth Hormone	ZORBTIVE	16.00%	\$1.75
Hemophilia	ADVATE	20.00%	\$1.75
Hemophilia	ALPHANATE	20.00%	\$1.75

THERAPEUTIC CLASS	BRAND NAME	AWP DISCOUNT %	DISPENSING FEE*
Hemophilia	ALPHANINE SD	20.00%	\$1.75
Hemophilia	AUTOPLEX	20.00%	\$1.75
Hemophilia	BEBULIN VH IMMUNO	20.00%	\$1.75
Hemophilia	BENEFIX	20.00%	\$1.75
Hemophilia	FEIBA VH IMMUNO	20.00%	\$1.75
Hemophilia	GENARC	20.00%	\$1.75
Hemophilia	HELIXATE FS	20.00%	\$1.75
Hemophilia	HEMOFIL-M	20.00%	\$1.75
Hemophilia	HUMATE-P	20.00%	\$1.75
Hemophilia	HYATE:C	20.00%	\$1.75
Hemophilia	KOATE-DVI	20.00%	\$1.75
Hemophilia	KOGENATE FS	20.00%	\$1.75
Hemophilia	MONARC-M	20.00%	\$1.75
Hemophilia	MONOCLATE-P	20.00%	\$1.75
Hemophilia	MONONINE	20.00%	\$1.75
Hemophilia	NOVOSEVEN	20.00%	\$1.75
Hemophilia	PROFILNINE	20.00%	\$1.75
Hemophilia	PROPLEX T	20.00%	\$1.75
Hemophilia	RECOMBINATE	20.00%	\$1.75
Hemophilia	REFACTO	20.00%	\$1.75
Hemophilia	STIMATE	20.00%	\$1.75
Hepatitis	COPEGUS	16.00%	\$1.75
Hepatitis	INFERGEN	16.00%	\$1.75
Hepatitis	INTRON A	16.00%	\$1.75
Hepatitis	PEGASYS	16.00%	\$1.75
Hepatitis	PEG-INTRON	16.00%	\$1.75
Hepatitis	REBETOL	16.00%	\$1.75
Hepatitis	REBETRON	16.00%	\$1.75
Hepatitis	ROFERON-A	16.00%	\$1.75
Hepatitis	RIBAVIRIN	45.00%	\$1.75
Hereditary Tyrosinemia	ORFADIN	0.00%	\$1.75
HIV	FUZEON	15.00%	\$1.75
Hyperparathyroidism	SENSIPAR	15.00%	\$1.75
Immune Deficiency	ACTIMMUNE	16.00%	\$1.75
Immune Deficiency	BAYGAM	16.00%	\$1.75
Immune Deficiency	BAYRHO-D	16.00%	\$1.75
Immune Deficiency	CARIMUNE	16.00%	\$1.75
Immune Deficiency	CYTOGAM	16.00%	\$1.75
Immune Deficiency	FLEBOGAMMA	16.00%	\$1.75
Immune Deficiency	GAMIMUNE N	16.00%	\$1.75
Immune Deficiency	GAMMAGARD	16.00%	\$1.75
Immune Deficiency	GAMMAR-P I.V.	16.00%	\$1.75
Immune Deficiency	GAMUNEX	16.00%	\$1.75
Immune Deficiency	IMMUNE GLOBULIN	16.00%	\$1.75
Immune Deficiency	IVEEGAM	16.00%	\$1.75
Immune Deficiency	MICRHOGAM	16.00%	\$1.75
Immune Deficiency	OCTAGAM	16.00%	\$1.75
Immune Deficiency	PANGLOBULIN	16.00%	\$1.75
Immune Deficiency	POLYGAM S/D	16.00%	\$1.75
Immune Deficiency	RESPIGAM	16.00%	\$1.75
Immune Deficiency	RHOGAM	16.00%	\$1.75

THERAPEUTIC CLASS	BRAND NAME	AWP DISCOUNT %	DISPENSING FEE*
Immune Deficiency	RHOPHYLAC	16.00%	\$1.75
Immune Deficiency	VENOGLOBULIN-S	16.00%	\$1.75
Immune Deficiency	WINRHO SDF	16.00%	\$1.75
Impotency	CAVERJECT	15.00%	\$1.75
Impotency	EDEX	15.00%	\$1.75
Impotency	MUSE	15.00%	\$1.75
Infertility	ADAGEN	0.00%	\$1.75
Infertility	A.P.L.	17.00%	\$1.75
Infertility	ANTAGON	17.00%	\$1.75
Infertility	BRAVELLE	17.00%	\$1.75
Infertility	CETROTIDE	17.00%	\$1.75
Infertility	CHOREX-10	17.00%	\$1.75
Infertility	CHORIONIC GONADOTROPIN	17.00%	\$1.75
Infertility	FERTINEX	17.00%	\$1.75
Infertility	FOLLISTIM/ANTAGON	17.00%	\$1.75
Infertility	FOLLISTIM/AQ	17.00%	\$1.75
Infertility	GANIRELIX ACETATE	17.00%	\$1.75
Infertility	GONAL-F	17.00%	\$1.75
Infertility	HUMEGON	17.00%	\$1.75
Infertility	LUVERIS	17.00%	\$1.75
Infertility	NOVAREL	17.00%	\$1.75
Infertility	OVIDREL	17.00%	\$1.75
Infertility	PERGONAL	17.00%	\$1.75
Infertility	PREGNYL	17.00%	\$1.75
Infertility	PROFASI	17.00%	\$1.75
Infertility	REPRONEX	17.00%	\$1.75
MS	AVONEX	15.00%	\$1.75
MS	BETASERON	15.00%	\$1.75
MS	COPAXONE	15.00%	\$1.75
MS	NOVANTRONE	15.00%	\$1.75
MS	REBIF	15.00%	\$1.75
MS	TYSABRI	15.00%	\$1.75
Mucopolysaccharidosis	ALDURAZYME	10.00%	\$1.75
Osteo-Arthritis	HYALGAN	15.00%	\$1.75
Osteo-Arthritis	ORTHOVISC	15.00%	\$1.75
Osteo-Arthritis	SUPARTZ	15.00%	\$1.75
Osteo-Arthritis	SYNISC	15.00%	\$1.75
Osteoporosis	FORTEO	15.00%	\$1.75
Psoriasis	AMEVIVE	15.00%	\$1.75
Psoriasis	RAPTIVA	15.00%	\$1.75
Pulmonary Hypertension	FLOLAN	0.00%	\$1.75
Pulmonary Hypertension	REMODULIN	0.00%	\$1.75
Pulmonary Hypertension	TRACLEER	10.00%	\$1.75
Rheumatoid Arthritis	ENBREL	15.00%	\$1.75
Rheumatoid Arthritis	HUMIRA	15.00%	\$1.75
Rheumatoid Arthritis	KINERET	15.00%	\$1.75
Rheumatoid Arthritis	REMICADE	15.00%	\$1.75
RSV	SYNAGIS	15.00%	\$1.75

\* If postage rates (i.e., U.S. mail and/or applicable commercial courier services) increase during the term of this Agreement, the Dispensing Fee will be increased to reflect such increase(s).

**SCHEDULE C**  
**SAMPLE MEMBER FUND ADDENDUM**

THIS ADDENDUM is entered into as of the \_\_\_\_ day of \_\_\_\_\_, \_\_\_\_ (the "Member Fund Addendum Effective Date") between Medco Health Solutions, Inc., located at 100 Parsons Pond Drive, Franklin Lakes, New Jersey 07417 ("Medco") and \_\_\_\_\_, located at \_\_\_\_\_ ("Member Fund").

WHEREAS, pursuant to the Integrated Prescription Drug Program Master Agreement (the "Agreement") dated as of July 1, 2005, between Medco Health Solutions, Inc., and The National Labor Alliance of Health Care Coalitions, Inc. ("NLAHCC"), those parties desire for prescription drug benefit services to be provided to Member Fund under this separate agreement addendum to be executed between Medco and the Member Fund; and

WHEREAS, Medco Health Solutions, Inc. provides prescription drug benefits programs and, in connection therewith, has established networks of participating retail pharmacies and operates a system for the processing, fulfillment and payment of claims for prescription drugs furnished by such pharmacies; and

WHEREAS, Medco Health Solutions, Inc.'s Medco By Mail mail order pharmacy subsidiaries are licensed pharmacies which provide prescription drugs via a mail order service; and

WHEREAS, NLAHCC and Participating Member Funds desire to retain the services of Medco Health Solutions, Inc. and its subsidiaries, including Medco, L.L.C., as applicable, which holds TPA licenses in certain states (collectively, "Medco"), to provide a prescription drug benefit program (the "Program") including, but not limited to, retail and mail order, and specialty pharmacy services for eligible persons, point-of-care, physician office communications, and cost containment initiatives developed and implemented by Medco, which may include communications with prescribers, patients and/or participating pharmacies, and financial incentives to participating pharmacies for their participation in such initiatives (collectively, "PBM Services").

NOW, THEREFORE, in consideration of the premises and the mutual covenants contained herein, the parties hereto agree as follows:

1. Member Fund agrees to be bound by all the terms of the Agreement (which is incorporated by reference), except as modified herein.
2. Notices - All notices required under this Addendum shall be in writing and sent by First Class mail, postage paid, facsimile or overnight delivery addressed as follows:

If to Medco:                      Medco Health Solutions, Inc.  
   100 Parsons Pond Drive  
   Franklin Lakes, NJ 07417  
   Attention: Thomas M. Moriarty  
   Vice President and Managing Counsel  
   Commercial Transactions

If to the Participating  
Member Fund:

3. Except as specifically modified by this Addendum, all of the terms of the Agreement will remain in effect. All capitalized terms used herein shall be defined as set forth in the Agreement, unless otherwise defined herein.

IN WITNESS WHEREOF, the parties have executed this Agreement as of the date indicated below.

**MEDCO HEALTH SOLUTIONS,  
INC.**

**PARTICIPATING MEMBER  
FUND**

BY: \_\_\_\_\_  
(signature)

BY: \_\_\_\_\_  
(signature)

NAME: Thomas M. Moriarty

NAME: \_\_\_\_\_  
(type or print name)

Vice President and Managing Counsel  
TITLE: Commercial Transactions

TITLE: \_\_\_\_\_

DATE: \_\_\_\_\_

DATE: \_\_\_\_\_



**SCHEDULE D**  
**PARTICIPATING MEMBER FUNDS CRITERIA**

**1. PARTICIPATING MEMBER FUND INFORMATION**

Each Participating Member Fund shall promptly furnish to Union Labor Life, who shall forward to Medco, in a format acceptable to Medco, all information necessary for Medco to render the services set forth herein for each Participating Member Fund. Such information shall include, but is not limited to:

- 1.1. A file of Eligible Persons, and subsequent timely additions and deletions to such file as changes occur. Each Participating Member Fund shall pay for any Covered Drug dispensed to a person reported by the Participating Member Fund to Union Labor Life as no longer an Eligible Person if such notification is not received by Medco from Union Labor Life at least two (2) full business days prior to the dispensing date of such prescription.
- 1.2. Designation, in writing, of those Plan Design features to be determined by each Participating Member Fund. The Plan Design, and any modifications thereto, are subject to the prior approval of Medco, which approval shall not be unreasonably withheld.
- 1.3. The reimbursement terms applicable to direct reimbursement claims submitted by Eligible Persons under the Retail Pharmacy Program.
- 1.4. The type, number and description of Identification Cards required for the Retail Pharmacy Program.

**2. BILLING/PAYMENT**

- 2.1. Union Labor Life shall provide each Participating Member Fund with a bi-weekly consolidated invoice for services provided by Medco Health under the Program, in accordance with the Program Pricing set forth in Schedule A. All invoices shall be paid in full by Union Labor Life to Medco Health within two (2) business days of receipt by wire transfer, electronic debit or other method approved by Medco Health in writing.
- 2.2. Each Participating Member Fund shall pay to Medco Health through Union Labor Life for administrative products and services provided by Medco Health under the Program in accordance with the Administrative Fee provisions set forth in Schedule A. Union Labor Life will provide each Participating Member Fund with an Administrative Fee invoice in accordance with Medco Health's four (4) week Administrative Fee cycle. Union Labor Life shall pay Administrative Fee invoices in full within fifteen (15) days of the invoice date.
- 2.3. Medco may revise the Program Pricing Terms set forth in Schedule A during the term of this Agreement upon sixty (60) days prior written notice to the NLAHCC and each Participating Member Fund. If any such Program Pricing Terms revision is unacceptable to the NLAHCC or such Participating Member Fund, the NLAHCC and the Participating Member Fund shall notify Medco, in writing, within fifteen (15) days of the NLAHCC and such Participating Member Fund's receipt of notice of the pricing revision. If the parties are unable to agree on mutually acceptable pricing, any party may terminate this Agreement upon sixty (60) days prior written notice to the other parties, provided such notice is given prior to the effective date of the proposed pricing revision.
- 2.4. Each Participating Member Fund through Union Labor Life shall pay to Medco, on or before its Member Fund Addendum Effective Date, a deposit equal to one (1) claims cycle's anticipated claims experience, which amount may be periodically modified by Medco based on each

Participating Member Fund's actual claims experience and enrollment. This deposit may be used by Medco to offset the failure by the Participating Member Fund, for any reason, to make any payments pursuant to the terms of this Agreement and does not, in any way, limit other remedies available to Medco. The deposit, to the extent not utilized to offset any payment default by that Participating Member Fund under this Agreement, shall be returned to that Participating Member Fund within one hundred eighty (180) days following termination of this Agreement.

- 2.5. Failure by any Participating Member Fund or Union Labor Life to make any payments in accordance with the terms of this Agreement shall constitute a payment default. Notwithstanding Section 10.2 of this Agreement, if the Participating Member Fund or Union Labor Life fails to cure any such payment default within two (2) days, in addition to other available remedies, Medco may terminate this Agreement upon notice to the Participating Member Fund. There shall be a late payment fee of 1% per month on the balance due on all late payments over two (2) days past due. A Participating Member Fund shall reimburse Medco for all collection costs incurred by Medco as a result of any payment default by that Participating Member Fund under this Agreement.

### 3. RECORDS

- 3.1. Medco will maintain all claims records relating to services performed under this Agreement as required by applicable law. Such claims records will be in their original form, on microfilm, microfiche, or other form determined by Medco. The NLAHCC's collective claims records may be audited, based on statistical sampling, or up to eight individual NLAHCC Participating Member Funds may perform individual claims audits, either directly or by a representative approved by Medco, subject to execution of a confidentiality agreement, for a maximum period of twenty-four (24) months prior to the agreed upon audit date, subject to applicable confidentiality provisions and legal requirements. Any audit by the NLAHCC or Participating Member Funds may be conducted once annually upon adequate prior written notice, and during regular business hours. Subject to Section 9.1 Medco may retain copies of such claims records for its own use. Medco's costs for any additional audits beyond the one collective audit or eight individual audits will be paid by NLAHCC or the Participating Member Funds.
- 3.2. Each Participating Member Fund shall furnish its most recent audited financial statement to Medco prior to its Member Fund Addendum Effective Date, and thereafter shall furnish its annual audited financial statement to Medco within ninety (90) days after the end of each fiscal year of each Participating Member Fund that this Agreement is in effect.

### 4. INDEMNIFICATION/LIMITATION OF LIABILITY

- 4.1. Medco agrees to indemnify and hold the NLAHCC and/or each Participating Member Fund, their officers, directors and employees (each an "Indemnified Party") harmless from claims or causes of action asserted against an Indemnified Party arising from services rendered by Medco pursuant to this Agreement to the extent the claim or cause of action arises out of Medco's, negligence or willful misconduct, provided that (a) the NLAHCC and/or the Participating Member Fund has given reasonable notice to Medco of the claim or cause of action, and (b) no Indemnified Party has, by act or failure to act, compromised Medco's position with respect to the resolution or defense of the claim or cause of action.
- 4.2. The NLAHCC and each Participating Member Fund agree to indemnify and hold Medco, its affiliates and their respective officers, directors and employees (each an "Indemnified Party") harmless from claims or causes of action asserted against an Indemnified Party arising from negligence or willful misconduct of the NLAHCC or any Participating Member Fund, including without limitation, the disclosure and/or use of Program data or information provided by Medco to the NLAHCC or any Participating Member Fund, provided that (a) the Indemnified Party has given reasonable notice to the NLAHCC and/or the Participating Member Fund of the claim or

cause of action, and (b) no Indemnified Party has, by act or failure to act, compromised the NLAHCC's or any Participating Member Fund's position with respect to the resolution or defense of the claim or cause of action.

- 4.3. Medco shall maintain, during the term of this Agreement, liability coverage with limits not less than \$1,000,000 per occurrence and in the aggregate per policy year, with excess liability coverage in an amount not less than \$5,000,000 per policy year. Evidence thereof shall be furnished to the NLAHCC or each Participating Member Fund upon request.
- 4.4. Except as provided in Section 4.1 above, in no event shall Medco or any affiliated company, or their directors, officers or employees be responsible in any manner for any claim, loss or damage sustained as a result of the provision of or failure to provide pharmaceutical goods or services or any other action or failure to act by any retail pharmacy or pharmaceutical providers pursuant to this Agreement.
- 4.5. The liability of Medco to each Participating Member Fund for any acts or omissions by Medco in the performance of their obligations hereunder shall be limited to the insurance amounts listed in Section 4.3 above.
- 4.6. In no event shall Medco, the NLAHCC or each Participating Member Fund be liable to each other for incidental, consequential or exemplary damages.

## 5. GENERAL

- 5.1. Independent Contractor - The relationship between Medco and each Participating Member Fund shall solely be that of independent contractors engaged in the operation of their own respective businesses.
- 5.2. Assignment - This Agreement may not be assigned by any party without the express prior written consent of the other parties which consent shall not be unreasonably withheld provided, however, that services to be performed by Medco hereunder may be performed by their subsidiaries, affiliates and/or designees.
- 5.3. No Third Party Beneficiary - This Agreement has been entered into solely for the benefit of each Participating Member Fund and Medco and is not intended to create any legal, equitable or beneficial interest in any third party or to vest in any third party any interest as to enforcement or performance.
- 5.4. Financial Responsibility - In the event Medco has reasonable grounds to believe that any Participating Member Fund may not meet its payment obligations under this Agreement or Member Fund Addendum as they become due, Medco may request information and/or reasonable assurances (including a deposit) from the Participating Member Fund as to its financial responsibility. In the event that such information or assurances are not furnished to Medco within five (5) days, or are not satisfactory in Medco's reasonable judgment, Medco may immediately terminate its Member Fund Addendum with that specific Participating Member Fund.
- 5.5. Plan Design - The Program Pricing Terms and the performance standards set forth in this Agreement and/or Member Fund Addendum are based upon the Plan Designs and Program specifications agreed to between the parties as reflected in this Agreement and/or Member Fund Addendum and as otherwise hereafter agreed to by the parties in writing. Any modification of the Plan Designs or Program specifications is subject to Medco's prior approval, which approval shall not be unreasonably withheld. Any such modification may result in a retroactive modification by Medco of the Program Pricing Terms and/or the performance standards. Each Participating Member Fund shall provide Eligible Persons with at least thirty (30) days prior notice of approved Plan Design changes.

- 5.6. Tax - Any applicable sales, use, or other similarly assessed and administered tax imposed on items dispensed, or services provided hereunder, will be the sole responsibility of the Participating Member Fund. If Medco is legally obligated to collect and remit sales, use, or other similarly assessed and administered tax in a particular jurisdiction, the tax will be reflected on the applicable invoice or subsequently invoiced at such time as Medco becomes aware of such obligation.

**SCHEDULE E**  
**NLAHCC MARKETING LANGUAGE**

- Medco, through its partnership with ULLICO, will support the branding of the NLAHCC relationship through the marketing of the *NLA Rx* prescription program.
- During the Initial Term of the Agreement, Medco will provide a marketing plan with committed resources for the sales and marketing of *NLA Rx* to the union marketplace.
- A \$100,000.00 allowance will be available for the documented cost of communication materials over three (3) year term.
- Medco (and its subsidiary Systemed) will commit to an expanded non-compete provision for NLAHCC identified groups up to 21,000 Eligible Persons.
- In further support of the partnership the *NLA Rx* product will be included as part of the Systemed portfolio during the Initial Term of this Agreement.

### **MEMBER FUND ADDENDUM**

**THIS ADDENDUM** is entered into as of the 1st day of October, 2005 (the "Member Fund Addendum Effective Date") between Medco Health Solutions, Inc., located at 100 Parsons Pond Drive, Franklin Lakes, New Jersey 07417 ("Medco Health") and New England Carpenters, located at 360 Fordham Road, Wilmington, MA 01887 ("Member Fund").

**WHEREAS**, pursuant to the Integrated Prescription Drug Program Master Agreement (the "Agreement") dated as of July 1, 2005, between Medco Health Solutions, Inc., and The National Labor Alliance of Health Care Coalitions, Inc. ("NLAHCC"), those parties desire for prescription drug benefit services to be provided to Member Fund under this separate agreement addendum to be executed between Medco Health and the Member Fund; and

**WHEREAS**, Medco Health Solutions, Inc. provides prescription drug benefits programs and, in connection therewith, has established networks of participating retail pharmacies and operates a system for the processing, fulfillment and payment of claims for prescription drugs furnished by such pharmacies; and

**WHEREAS**, Medco Health Solutions, Inc.'s home delivery pharmacy subsidiaries are licensed pharmacies which provide prescription drugs via a home delivery service; and

**WHEREAS**, Member Fund desires to retain the services of Medco Health to provide a managed care prescription drug benefit program (the "Program") consisting of retail and mail service pharmacy services for eligible persons pursuant to the terms and provisions contained in the Agreement and herein, and cost containment initiatives developed and implemented by Medco Health which may include communications with prescribers, patients and/or participating pharmacies, and financial incentives to participating pharmacies for their participation in such initiatives.

**NOW, THEREFORE**, in consideration of the premises and the mutual covenants contained herein, the parties hereto agree as follows:

1. Member Fund agrees to be bound by all the terms of the Agreement (which is incorporated by reference), except as modified herein.
2. Notices - All notices required under this Addendum shall be in writing and sent by First Class mail, postage paid, facsimile or overnight delivery addressed as follows:

If to Medco Health:     Medco Health Solutions, Inc.  
                                 100 Parsons Pond Drive  
                                 Franklin Lakes, NJ 07417  
                                 Attention: Thomas M. Moriarty  
                                 Vice President and Managing Counsel  
                                 Commercial Transactions

If to the Participating  
Member Fund:

3. Section 4.5 of Schedule D of the Agreement is revised as follows:
  - 4.5 The liability of Medco Health to each Participating Member Fund for any acts or omissions by Medco Health in the performance of its obligations hereunder shall be limited to the liability insurance amounts set forth in Section 4.3 above.
4. Except as specifically modified by this Addendum, all of the terms of the Agreement will remain in effect. All capitalized terms used herein shall be defined as set forth in the Agreement, unless otherwise defined herein.

IN WITNESS WHEREOF, the parties have executed this Agreement as of the date indicated below.

**MEDCO HEALTH SOLUTIONS, INC.**

**PARTICIPATING MEMBER FUND**

BY: \_\_\_\_\_  
(signature)

BY: \_\_\_\_\_  
(signature)

NAME: Thomas M. Moriarty

NAME: James Buckley  
(type or print name)

Vice President and Managing Counsel  
TITLE: Commercial Transactions

TITLE: \_\_\_\_\_

DATE: \_\_\_\_\_

DATE: \_\_\_\_\_

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# **Exhibit 16D**





The New England Carpenters  
Health Benefits Fund

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# HEALTH BENEFITS FUND | GREAT BENEFITS FOR LIFE

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SUMMARY PLAN  
DESCRIPTION | NEW ENGLAND CARPENTERS

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NEW ENGLAND  
CARPENTERS  
HEALTH  
BENEFITS  
FUND

As a member of the New  
England Carpenters Health  
Benefits Fund, you and your  
family are eligible for a  
generous benefits package  
that offers you well-being,  
security and protection.

NEW ENGLAND  
CARPENTERS  
HEALTH  
BENEFITS  
FUND



## Health Benefits Fund

**The New England Carpenters Health Benefits Fund**

350 Fordham Road  
Wilmington, MA 01887  
Phone: (800) 344-1515  
Fax: (978) 657-8724

August 2005

**Dear Participant:**

The Board of Trustees of the New England Carpenters Health Benefits Fund is pleased to issue this revised Summary Plan Description. This handbook has been written to reflect the changes in the Health Benefits Fund since the last version was printed.

As your Board of Trustees, we continually evaluate the benefits for opportunities for enhancement while maintaining a financially sound Health Benefits Fund. When we design our benefit programs and make improvements, we try to do what's best for the participants. This revised Summary Plan Description is a reflection of our efforts.

Note that medical benefits and weekly accident and sickness benefits are provided directly by the Fund. Life insurance and accidental death and dismemberment benefits are underwritten by Hartford Life Insurance Company.

***A New Approach***

This book has been designed to be easy to read and understand. "Fast Facts" appear at the beginning of each section to give you a quick overview of what is contained within that section. Also, useful information—such as phone numbers and definitions—appear in the margin as a quick reference.

In addition, this book provides the required information about your rights and protection under the law in order to comply with the Employee Retirement Income Security Act of 1974 (ERISA). This information is on page 67.

We encourage you and your family to read this Summary Plan Description carefully to make the best use of the benefits the New England Carpenters Health Benefits Fund offers.

If you have any questions concerning the benefits or your eligibility, please feel free to contact the Fund Office at (800) 344-1515.

Sincerely,  
Board of Trustees

## BOARD OF TRUSTEES

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### Employer Trustees

William J. Sullivan  
*Secretary/Treasurer*

Stephan A. Adamic  
*Co-Secretary/Treasurer*

George M. Bidgood

Theodore H. Brodie

Donald L. Colavecchio

Thomas J. Gunning

Michael Shaughnessy

William Shea

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Thomas J. Flynn

Simon R. James

Bruce King

John Murphy

Michael Nelson

David Wallace

Jack Winfield

David A. Woodman

---

### Executive Director

Harry R. Dow

### Director and Field Representative

James W. Buckley, Jr.

### Legal Counsel

O'Reilly, Grosso & Gross

Krakow & Souris, LLC.

### Consultants and Actuaries

The Segal Company

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*The Board of Trustees reserves the right to terminate or amend the Plan at any time. This includes the right to amend or terminate benefits or eligibility for any class of participant, including retirees, when in their sole discretion the Board determines such action is in the best interest of the Fund and its participants.*

*Changes to your plan of benefits can happen at any time, so if you have a question about a particular service or program, contact the Fund Office for the most up-to-date information.*

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## KEY CONTACT PHONE NUMBERS AND ADDRESSES

Benefit	Address	Phone Number	Website
Medical Care	The Fund Office 350 Fordham Road Wilmington, MA 01887	978-694-1000 800-344-1515	<a href="http://www.carpentersfund.org">www.carpentersfund.org</a>
Dental Care	Delta Dental 485 Medford Street Boston, MA 02129	800-822-0500	<a href="http://www.deltadental.com">www.deltadental.com</a>
Vision Care	Carpenters Vision Center 250 Everett Street Allston, MA 02134	917-782-0100	
	Davis Vision 159 Express St. Plainville, NY 11803	800-999-5431 TTY: 800-523-2847	<a href="http://www.davisvision.com">www.davisvision.com</a>
Prescription Drugs	Uicare Rx/Medco 100 Parsons Pond Drive Franklin Lakes, NJ 07417	800-818-6602	<a href="http://www.medcohealth.com">www.medcohealth.com</a>
Carpenters Assistance Program	350 Fordham Road Wilmington, MA 01887	978-694-1000 800-344-1515	
Health Management Program (Preauthorization)	Hines & Associates	800-944-9401	<a href="http://www.hinesassoc.com">www.hinesassoc.com</a>

## **YOUR HEALTH BENEFITS FUND**

5 |

The New England Carpenters Health Benefits Fund offers eligible members and their families comprehensive health care coverage. Benefits include office visits, hospitalization and surgery, home health care, coverage for prescription drugs, mental health and substance abuse treatment, dental and vision care.

You want the comfort of knowing that your family will be protected if something happens to you. Eligible members qualify for a life insurance benefit, accidental death and dismemberment insurance benefits and weekly accident and sickness benefits. The Fund also offers an extension of medical benefits for you and your family if you become disabled, or for your family—at no charge—in the event of your death.

### **HOW THE HEALTH BENEFITS FUND WORKS**

The Health Benefits Fund contains three comprehensive health care plans, which offer coverage depending on your eligibility:

- **PLAN I**, for active members and their dependents;
- **PLAN II**, for active members and their dependents; and
- **THE RETIREE PLAN**, for eligible retirees and their dependents.

## ELIGIBILITY

### FAST FACTS:

- You must work a specified number of hours in a six-month work period to be able to initially participate in the Plan.
- You must also work a specified number of hours to be eligible to receive benefits for you and /or your eligible dependents.
- When you don't work enough hours to qualify for benefits, you may be able to purchase Continuation Coverage under the Federal program known as COBRA.
- When you retire, you may be able to purchase coverage under the Retiree Plan if you meet all the requirements.

### What is Covered Employment?

Covered employment is work you do for which contributions are made by a contributing employer under the terms of a collective bargaining agreement or signed participation agreement.

### What is a Collective Bargaining Agreement?

A Collective Bargaining Agreement is a written agreement between a union and an employer that requires the employer to make contributions to the Fund on behalf of its employees.

Your eligibility to participate in Plan I or Plan II is based on the number of hours you work in covered employment and the contribution rate your employer is required to make to the Fund on your behalf. Plan I offers coverage for members that work 600 hours or more in a six-month period. Plan II offers a lower level of coverage for members that work at least 350 hours (but fewer than 600) in a six-month period. These rates are outlined in a Collective Bargaining Agreement between your employer and the New England Carpenters Health Benefits Fund.

### Hours Requirements

Your eligibility for benefits—which is different from your eligibility to participate—depends on the number of hours you work in covered employment during a six-month “work period.” If you work the required number of hours—and your employer contributes to the Fund for those hours—you and your eligible dependents will be eligible for coverage for six months. The hours requirements for a six-month work period are:

- Plan I—600 hours in one work period or 1,250 hours in two consecutive work periods.
- Plan II—350 hours in one work period
- Local 1996
  - Plan I— 750 hours in one work period or 1,550 hours in two consecutive work periods.
  - Plan II— 425 hours in one work period.

### Work Periods and Coverage Periods

There are two work periods per year. The hours you work during the work period are used to determine whether you're eligible for coverage during the six-month coverage period. Coverage periods begin on April 1 or October 1.

Review Date	If you work the required hours during the work period...	You'll be eligible for coverage during the coverage period.
April 1	August, September, October, November, December and January	April, May, June, July, August and September
October 1	February, March, April, May, June and July	October, November, December, January, February and March



## **MAINTAINING YOUR ELIGIBILITY**

Once you gain eligibility, that will continue as long as you work at least 600 hours (Plan I) or 350 hours (Plan II) in the six-month work period prior to the coverage period.

If you do not work the required number of hours, you may be able to maintain your coverage, as explained below, by:

- "Buying-In" to the Fund; or
- Using the banked hours you've accumulated in your Hours Bank for hours worked before 1989. Banked hours are removed once you retire.

### **Plan I — Active Members**

Plan I members may continue coverage provided they work at least 1,250 hours in the previous two consecutive six-month work periods preceding the period they were covered.

#### **Local 51 and Shops in Plan I Only**

Shop employers contribute a set dollar amount for hours worked in the current month to be covered for the following month. Members must work one hour and the employer must make the monthly contribution to be covered. For example, a member who works one hour in May is entitled to full Plan I coverage for the month of June.

## **IF YOU'RE SHORT OF HOURS**

If you do not qualify for continued coverage based on your hours worked, coverage may be continued in two other ways—through the use of a Buy-In or Banked Hours.

### **Short Hours Buy-In**

If you do not work enough hours during a work period to maintain your eligibility, you may purchase Buy-In coverage if you were short by 30 hours or less. In order to take advantage of the buy-in provision, you must have been eligible during the preceding coverage period under that plan with worked hours only.

You may buy into the plan of coverage you were eligible for in the prior coverage period at the special buy-in rate per hour. For example, if you are in Plan I and you had worked at least 570 hours, you could buy the 30 hours you were short (600 required – 570 worked) for the buy-in rate times 30. To buy into Plan II coverage, you must work at least 320 hours in a work period. For the most up-to-date buy-in rate, contact the Fund Office.

Payment must be made in one lump sum. You have only until the end of April or October to choose this buy-in option. Otherwise, continuation coverage would be available under COBRA at COBRA rates. (See page 11 for information on COBRA Continuation Coverage.) If late hours are received and would bring you into 30 hours short, you would have 30 days from the date of notification to choose this buy-in option.

### **Special Rule for New Members**

New members may buy into Plan II after working eight hours in the current work period.

An eligibility statement with the monthly cost will be mailed to you in March or September (the end of the insured period) indicating the cost for coverage starting the following month, the next coverage period. Be sure to keep your address current with the Fund Office so you can receive this statement.

#### **Banked Hours**

Hours that were banked prior to August 1, 1989, may be drawn upon to maintain your coverage when you do not work the required number of hours in a work period for active members. You will be permitted to use hours from your bank to continue eligibility, provided you worked some hours in covered employment during the previous or current work period. You must be eligible to buy into COBRA to exercise this option.

Banked hours are credited at \$1.90, which was the actual dollar value of the contribution rate in effect at the time the hours were banked. Therefore, the total banked hours used to maintain eligibility will reduce the actual cost of the insurance coverage.

- To use your banked hours, you must indicate your wishes on a COBRA form (continuation coverage) or send a letter of request to the Fund Office.

#### **Proving Eligibility for Dependents**

You are required to furnish the following documentation for dependent coverage if you have not already done so:

- Marriage certificate from City Hall or Town Hall;
- Birth certificate document showing both parents' names, court document or written statement on letterhead from appropriate governmental agency showing legal guardianship and date of birth of each child;
- Divorce decree if applicable;
- Proof of a dependent child's attendance at an accredited school or college as a full-time student upon attainment of age 19 must be submitted to the Fund Office twice each year, as directed by the Fund Office, on an original form which contains the accredited institution's seal. He or she must provide a letter from the registrar.

The letter should include:

- Verification of his or her enrollment;
- The number of course hours for which he or she is enrolled; and
- The beginning and ending dates of the term.

#### **ELIGIBLE DEPENDENTS**

When you become eligible for coverage in the New England Carpenters Health Benefits Fund, your eligible dependents are also eligible for coverage.

#### **Plan's Definition of Dependent**

The term "dependent" means (1) your lawful spouse; (2) your unmarried children (including a legally adopted child) who are under 19 years of age; and your unmarried children who are at least 19 but less than 24 years of age who are enrolled as full-time students in an accredited school, college or university, not employed on a full-time basis and dependent upon you for financial support.

#### **If Your Child is Disabled**

If an unmarried dependent child is incapable of self-sustaining employment because of physical handicap or mental retardation and he or she is dependent upon you for support and maintenance, his/her coverage will be continued provided his/her incapability commenced prior to attaining age 19 or age 24 if a full-time student. You must submit proof of your dependent child's incapability to the Fund Office on the later of 31 days after the date he/she attains 19 years of age or age 24 if a full-time student or 31 days after you are notified of his/her eligibility. Benefits will continue to be provided for your child as long as you remain covered under the Fund.

No person may be eligible for benefits both as a member and as a dependent.

Proof of the continued existence of such incapability shall be furnished to the Fund Office yearly.

The term "child" also includes a stepchild or foster child, provided the child depends upon you for support and maintenance and has been reported to the Fund Office.

**What You Need to Do**

If you are adopting a child, the following is needed:

- A copy of the birth certificate once it is available;
- A copy of the paperwork from the adoption agency showing the date the child was placed in the home. (Coverage for an adopted child will begin on the date the child was placed in the home.)

If you are the legal guardian, the following is needed:

- A copy of the birth certificate;
- A copy of the court document stating that the member is the legal guardian of the child. (Coverage will begin on the date of the legal document.)

If you have not adopted the child or do not have legal guardianship and are only the stepparent by marriage, then the following is needed:

- A copy of the birth certificate;
- A copy of the natural parent's divorce decree, the medical insurance section, along with the front page that has the name of the defendant and plaintiff's names.

- A copy of the tax return.

See page 20 for more information.

**When Coverage Ends**

Your dependents' eligibility for coverage will end on:

- The date your child or spouse no longer meets the definition of an eligible dependent under the Fund; or
- The date your eligibility ends.

**IF YOUR CHILD'S ELIGIBILITY FOR BENEFITS CHANGES**

If your child's eligibility status changes, you must notify the Fund Office as soon as possible.

Your child may be eligible for COBRA Continuation Coverage for up to 36 months. See page 11 for more information.

**EXTENSION OF BENEFITS FOR TOTALLY DISABLED MEMBERS**

If you become totally disabled while covered for benefits under this Fund, you may be eligible for an extension of benefits for up to two consecutive coverage periods. Your coverage will be under the same Plan you had at the time of your disability, subject to proper documentation. This option is available only once per lifetime. If only one free coverage period is required, the option for a second coverage period is voided. Contact the Fund Office for an Extension of Benefits form.

If you are eligible for a Social Security Disability Pension, you may be eligible for coverage under the Retiree Health Benefits Plan for up to 24 months or until you are covered by Medicare, whichever comes first.

**Widow(er) Extension**

If a member is covered by this Fund under worked hours or buying into Plan I at the time of his or her death, the surviving spouse and eligible dependents will be covered by the Fund for a maximum of three additional years under Plan I. Coverage is provided at no premium cost, provided that the spouse and dependents have no other health insurance, including Medicare. However, if the member was buying into Plan II at the time of his or her death, the surviving spouse and eligible dependents are only eligible for coverage under Plan II.

**WHEN COVERAGE ENDS**

Generally, your coverage under the New England Carpenters Health Benefits Fund will end:

- For Shop Employees, the first day of the following month in which you stop working in covered employment;
- The date you do not meet the requirements for eligibility; or
- The date the Plan terminates.

**What You Need To Do**

If your child is no longer eligible for coverage under the Fund, he or she may elect to continue coverage under COBRA. You or your child must:

- Contact the Fund Office within 60 days of losing eligibility; and
- Enroll in COBRA Continuation Coverage. Failure to contact the Fund Office and provide notice of the "Qualifying Event" (discussed in more detail on page 11) will result in a loss of rights to COBRA.

These same rules apply to a Spouse who loses coverage due to a separation or divorce.

**Continuing Your Coverage Under COBRA**

When your coverage under this Fund ends, you may be eligible to continue some of the same coverage you had under the Health Benefits Fund for a limited time under COBRA. For information about COBRA Continuation Coverage, see page 11.

**RETIREE HEALTH BENEFITS PLAN**

If you retire on or after April 1, 1995, with a Service, Normal, Early or Disability Pension and meet the Plan's other eligibility requirements, you and your eligible dependents are eligible for the New England Carpenters Retiree Health Benefits Plan. There are five requirements:

- You must be eligible for five out of the past ten coverage periods, have 3,000 hours during the five-year period immediately prior to retirement and be covered by the Plan in the period immediately preceding your application for retiree coverage.
- You must have no other group health insurance, including Medicare.
- You must share the cost of coverage with the Fund. Your monthly premiums will increase from time to time.
- You must obtain medical services from providers in the Carpenters Preferred Provider Network unless you do not live within a 20-mile radius of the nearest network provider.
- You must obtain pre-certification for all inpatient hospital stays.

**Continued Eligibility for Retirees**

Eligibility to participate ends on the earlier of:

- The last day of the month when you do not pay the premium when required;
- The date your pension benefit is suspended for any reason;
- The date you become eligible under another group health plan;
- The date you or your eligible dependent become entitled to Medicare; or
- The date the Plan terminates.

Local 108 cannot participate in the Retiree Plan.

**Eligibility for Widow(ers) and Dependent Children**

If you were eligible for a Service, Normal, Early or Disability Pension from the New England Carpenters Pension Fund at the time of your death, your widow(er) and eligible dependent children may continue coverage under the Retiree Health Plan on a self-payment basis. If a dependent child is covered under a member who is purchasing the Retiree Health Plan and the child reaches the age limit, the dependent is eligible to buy into Plan II under COBRA.

## CONTINUING YOUR COVERAGE

### FAST FACTS:

- You and your dependents may continue certain medical benefits if your coverage ends due to a "Qualifying Event."
- Your children are eligible to continue coverage under COBRA when they no longer satisfy the Fund's definition of eligible dependent because of age, marriage or student status.
- To keep your coverage under COBRA, you must make monthly payments to the Fund Office on time. You are fully responsible for the payment of your benefits through COBRA.

### COBRA CONTINUATION COVERAGE

If your coverage under the New England Carpenters Health Benefits Fund ends due to a "Qualifying Event" (see below), you and/or your covered dependents may be eligible to continue your health care coverage under the Consolidated Omnibus Budget Reconciliation Act of 1985 (COBRA).

By making monthly payments, you and/or your dependents may continue the same medical, dental, vision and prescription drug coverage that you had before your coverage ended. Your coverage can last for up to 18, 29 or 36 months, depending on the Qualifying Event that resulted in your loss of coverage.

#### Qualifying Events

To be eligible to elect COBRA Continuation Coverage, you (as the member) and/or your dependent(s) must lose coverage due to any one of the Qualifying Events, which are listed in the first column in the table below. The last column indicates how individuals find out that they're eligible for continuation coverage, which are explained below.

Qualifying Event	Who May Purchase (Qualified Beneficiary)	Eligibility	Notification Requirements
Member terminated for other than gross misconduct (including retirement)	Member, spouse and/or dependent children	18 months	Fund Office will advise eligible participants
Member reduction in hours worked (making Member ineligible for coverage or the same coverage under the Plan)	Member, spouse and/or dependent children	18 months	Fund Office
Member becomes entitled to Medicare	Spouse and/or dependent children	36 months	Fund Office will advise eligible participants when member reaches 65. If member becomes eligible before 65, he or she must advise Fund Office
Member becomes eligible for disability through Social Security	Member, spouse and/or children	11 months in addition to the 18 months	Member must advise Fund Office
Death of Member	Spouse and/or dependent children	36 months minus the number of months covered since the divorce	Family member must notify Fund Office
Member is divorced or legally separated from spouse	Spouse and/or dependent children	36 months	Member or Spouse must advise Fund Office so notification can occur
Child ceases to be a dependent child under Plan definition	Dependent child	36 months	Member must advise Fund Office so notification can occur

**Who May Elect COBRA?**

Under the law, only "Qualified Beneficiaries" are entitled to elect COBRA Continuation Coverage. A Qualified Beneficiary is any member, his or her spouse or dependent who was covered by the New England Carpenters Health Benefits Fund when a Qualifying Event occurs. A child who becomes a dependent child by birth, adoption or placement for adoption with the Member during a period of COBRA Continuation Coverage is also a qualified beneficiary. However, a dependent purchasing COBRA who acquires a spouse during COBRA Continuation Coverage is not a qualified beneficiary.

- !! One or more of your family members may elect COBRA even if you do not. Additionally, one member may elect COBRA for all Qualified Beneficiaries. However, in order to elect COBRA Continuation Coverage, the members of the family must have been covered by the Plan on the date of the Qualifying Event. A parent may elect or reject COBRA Continuation Coverage on behalf of dependent children living with him or her.

**How to Elect COBRA Continuation Coverage**

- In order to elect COBRA Continuation Coverage, the Fund Office must be notified when you experience a Qualifying Event. You must notify the Fund Office within 60 days from the date that the Qualifying Event occurs, or the date that you would lose coverage under the Fund because of the Qualifying Event, whichever is later. See the following Notification Procedures.
- When the Fund Administrator receives notice of the Qualifying Event, he or she will mail you an election form, information about COBRA and the date on which your coverage will end.

Under the law, you and/or your covered dependents have 60 days from the later of the date:

- You would have lost coverage because of the Qualifying Event; or
- You and/or your covered dependents received the election form and COBRA information.

If you and/or any of your covered dependents do not elect COBRA within 60 days of the Qualifying Event (or, if later, within 63 days from the mailing date), you and/or your covered dependents will not have any group health coverage from this Fund after your coverage ends.

**COBRA Notification Procedures**

As a covered Member or Qualified Beneficiary you are responsible for providing the Fund Administrator with timely notice of certain qualifying events. You must provide the Fund Administrator notice of the following qualifying events:

- The divorce or legal separation of a covered Member from his or her spouse.
- A beneficiary ceasing to be covered under the Plan as a dependent child of a member.
- The occurrence of a second qualifying event after a Qualified Beneficiary has become entitled to COBRA with a maximum of 18 (or 29) months. This second qualifying event could include a Member's death, entitlement to Medicare, divorce or legal separation or child losing dependent status.

In addition to these qualifying events, there are two other situations when a covered Member or Qualified Beneficiary is responsible for providing the Fund Administrator with notice within the timeframe noted in this section:

- When a Qualified Beneficiary entitled to receive COBRA coverage with a maximum of 18 months has been determined by the Social Security Administration to be disabled. If this determination is made at any time during the first 60 days of COBRA coverage, the Qualified Beneficiary may be eligible for an 11-month extension of the 18 months maximum coverage period, for a total of 29 months of COBRA coverage.
- When the Social Security Administration determines that a Qualified Beneficiary is no longer disabled.

You must make sure that the Fund Administrator is notified of any of these five occurrences listed above. Failure to provide this notice within the form and timeframes described below may prevent you and/or your dependents from obtaining or extending COBRA coverage.

**How Should a Notice Be Provided?**

In order to provide the Fund notice of any of these five situations you must complete and sign the Fund's "COBRA Notice Form for Covered Employees and Qualified Beneficiaries." You can obtain a copy of the form by calling the Fund Office at (800) 344-1515.

Alternatively, you may send a letter to the Fund containing the following information: your name, for which of the five events listed above you are providing notice, the date of the event, the date in which the participant and/or beneficiary will lose coverage.

**To Whom Should the Notice Be Sent?**

Notice should be sent to the Fund at the following address:

Director and Field Representative  
The New England Carpenters Health Benefits Fund  
PO Box 7075  
Wilmington, MA 01887  
Phone: (800) 344-1515  
Fax: (978) 657-8724

**When Should the Notice Be Sent?**

If you are providing notice due to a divorce or legal separation, a dependent losing eligibility for coverage or a second qualifying event, you must send the notice no later than 60 days after the later of (1) the date upon which coverage would be lost under the Plan as a result of the qualifying event (2) the date of the qualifying event or (3) the date on which the Qualified Beneficiary is informed through the furnishing of a summary plan description or initial COBRA notice of the responsibility to provide the notice and the procedures for providing this notice to the Fund Administrator.

If you are providing notice of a Social Security Administration determination of disability, notice must be sent no later than the end of the first 18 months of continuation coverage.



**Notify The Fund Office**

You or a family member should notify the Fund Office when any Qualifying Event occurs to avoid confusion over the status of your health care in the event that your Employer does not provide prompt or correct information.

If you are providing notice of a Social Security Administration determination that you are no longer disabled, notice must be sent no later than 30 days after the later of (1) the date of the determination by the Social Security Administration that you are no longer disabled or (2) the date on which the Qualified Beneficiary is informed through the furnishing of a summary plan description or initial COBRA notice of the responsibility to provide the notice and the procedures for providing this notice to the Fund Administrator.

**Who Can Provide a Notice?**

Notice may be provided by the covered Member, Qualified Beneficiary with respect to the qualifying event, or any representative acting on behalf of the covered Member or Qualified Beneficiary. Notice from one individual will satisfy the notice requirement for all related qualified beneficiaries affected by the same qualifying event. For example, if a member and his or her spouse and child are all covered by the Plan, and the child ceases to become a dependent under the Plan, a single notice sent by the spouse would satisfy this requirement.

Where you or your dependents have provided notice to the Fund Administrator of a divorce or legal separation, beneficiary ceasing to be covered under the Plan as a dependent or a second qualifying event, but are not entitled to COBRA, the Fund Administrator will send you a written notice stating the reason why you are not eligible for COBRA.

**Paying for COBRA Continuation Coverage**

You are responsible for the entire cost of COBRA Continuation Coverage. When you and/or your dependents become eligible for this coverage, the Fund Administrator will notify you of the COBRA premium amounts that you must pay.

Your COBRA premiums may be as high as 102% of the Plan's cost, except in the case of Social Security disability. (See the section below entitled "COBRA Continuation Coverage for Disabled Participants.")

You must send the first COBRA payment to the Fund Office within 45 days from the date on which the Fund Office receives your COBRA election form, as determined by postage cancellation. You must make payments so that coverage is continuous—there can be no lapse in coverage. If you choose COBRA within the election period but after the date on which your eligibility ended, you must pay the required COBRA premiums retroactively to cover the elapsed period.

**Late COBRA Payments**

Your monthly payments are due on the 1st day of each month. You will have 30 days in which to pay. Payments should be mailed to the Fund Office. If you do not make payment by the end of the 30 days, your coverage will be cancelled retroactively to the last day of the previous month and you will lose your right to continuation coverage.

**What You Need To Do:**  
If you lose coverage due to a Qualifying Event:

- Inform the Fund Office of the Qualifying Event and request a COBRA election form.
- Complete and mail back the election form within 63 days of the date of the mailing, or 60 days of the date the Qualifying Event occurred, whichever is later.
- Make your first payment to the Fund Office within 45 days from the date the Fund Office receives your COBRA election form.



**COBRA Continuation Coverage for Disabled Participants**

If you are covered under COBRA for 18 months, and within the first 60 days of coverage you (or your covered dependent) become disabled, you (and your Qualified Beneficiaries who elected COBRA) may be eligible to continue your COBRA coverage for an additional 11 months for a total of 29 months.

To be eligible, the Social Security Administration must make a formal determination that you (or your dependent) were disabled effective within the initial 60-day period of the start of your COBRA coverage and therefore entitled to Social Security Disability income benefits. You (or your dependent) must notify the Fund Office of the Social Security determination of disability by the end of the 18-month initial COBRA period if you wish to continue with the 11-month extension.

If you are eligible for the 11-month extension, your COBRA premiums may be as high as 150% of the regular premiums for the additional 11 months of coverage.

This extended period of COBRA coverage will end on the earlier of:

- The last day of the month that occurs 30 days after Social Security has determined that you and/or your dependent(s) are no longer disabled;
- The end of the 29 months' COBRA Continuation Coverage;
- The date the disabled person becomes entitled to Medicare.

If you recover from your disability before the end of the initial 18 months of COBRA Continuation Coverage, you will not have the right to purchase extended coverage. You must notify the Fund Office within 30 days of:

- The date that you receive a final Social Security determination that you and/or your dependent(s) are no longer disabled; or
- The date that the disabled person becomes entitled to Medicare.

**Multiple Qualifying Events While Covered Under COBRA**

The maximum period of coverage under COBRA is 36 months, even if you experience another Qualifying Event while you're already covered under COBRA. If you're covered under COBRA for 18 months because of your termination of employment or reduction in hours, your affected spouse or dependent may extend coverage for another 18 months in the event of your death or if:

- You get divorced or legally separated;
- You become entitled to Medicare; or
- Your child is no longer a dependent under the Fund's definition.

*For example, you stop working (the first COBRA-Qualifying Event), and you enroll yourself and your dependents for COBRA Continuation Coverage for 18 months. Three months after your COBRA Continuation Coverage begins, your child turns 19 and no longer qualifies as a dependent child under the Fund's definition. Your child then can continue COBRA coverage separately for an additional 33 months, for a total of 36 months' COBRA Continuation Coverage.*

You, as the member, are not entitled to COBRA Continuation Coverage for more than a total of 18 months if your employment is terminated or you have a reduction in hours (unless you are entitled to additional COBRA Continuation Coverage on account of disability). Therefore, if you experience a reduction in hours followed by a termination of employment, the termination of employment is not treated as a second Qualifying Event and you may not extend your coverage.

**Coverage for Your Dependents if You're Enrolled in Medicare**

If you are entitled to or enrolled in Medicare and you have a termination of employment or reduction in hours, your eligible dependents would be entitled to COBRA for a period of 18 months (29 months if the 11-month Social Security Disability extension applies) from the date of your termination of employment or reduction in hours or 36 months from the date you became entitled to Medicare, whichever is longer.

**Special COBRA Enrollment Rights**

If you marry, have a newborn child, adopt a child or have a child placed with you for adoption while you are enrolled in COBRA, you may enroll that spouse or child for coverage for the balance of the period of COBRA Continuation Coverage. You must enroll your new dependent within 31 days of the marriage, birth, adoption or placement for adoption, with proper documentation.

In addition, if you are enrolled for COBRA Continuation Coverage and your spouse or dependent child loses coverage under another group health plan, you may enroll that spouse or child for coverage for the balance of the period of COBRA within 31 days after the termination of the other coverage.

To be eligible for this special enrollment right, your spouse or dependent child must have been eligible for coverage under the terms of the Plan but declined when enrollment was previously offered because they had coverage under another group health plan or had other health insurance coverage, with proper documentation.

**Confirmation of Coverage to Health Care Providers**

Under certain circumstances, federal rules require the Fund to inform your physician and health care providers as to whether you have elected and/or paid for COBRA Continuation Coverage. This rule only applies in certain situations where the physician or provider is requesting confirmation of coverage and you are eligible for, but have not yet elected, COBRA coverage, or you have elected COBRA coverage but have not yet paid for it.

**Termination of COBRA Continuation Coverage**

COBRA Continuation Coverage will terminate on the last day of the maximum period of coverage unless it is cut short for any of the following reasons:

- You do not make all required payments on time;
- The person receiving the coverage becomes covered by another group health plan that does not contain any legally applicable exclusion or limitation with respect to pre-existing conditions that the covered person may have;

- The person receiving the coverage becomes entitled to Medicare;
- The Plan terminates its group health plan and no longer provides group health insurance coverage to its members; or
- The Employer that employed you prior to the Qualifying Event has stopped contributing to the Plan; and
- The Employer establishes one or more group health plans covering a significant number of the employer's employees formerly covered under this Plan; or
- The Employer starts contributing to another multiemployer plan that is a group health plan.

If continuation coverage is terminated before the end of the maximum coverage period, the Fund Administrator will send you a written notice as soon as practicable following the Fund Administrator's determination that continuation coverage will terminate. The Notice will set out why continuation coverage will be terminated early, the date of termination, and your rights, if any, to alternative individual or group coverage.

☛ If you have questions about COBRA Continuation Coverage, contact the Fund Office at (800) 334-1515.

**Additional COBRA Election Period and Tax Credit in Cases of Eligibility for Benefits Under the Trade Act of 1974**

If you are certified by the U.S. Department of Labor (DOL) as eligible for benefits under the Trade Act of 1974, you may be eligible for both a new opportunity to elect COBRA and an individual Health Insurance Act Credit. If you and/or your dependents did not elect COBRA during your election period, but are later certified by the DOL for Trade Act benefits or receive pensions managed by the Pension Benefit Guaranty Corporation (PBGC), you may be entitled to an additional 60-day COBRA election period beginning on the first day of the month in which you were certified. However, in no event would this benefit allow you to elect COBRA later than six months after your coverage ended under the Plan.

Also under the Trade Act, eligible individuals can either take a tax credit or get advance payment of 65% of premiums paid for qualified health insurance, including continuation coverage. If you have questions about these tax provisions, you may call the Health Care Tax Credit Customer Contact Center toll-free at 1-866-628-4282. TTD/TTY callers may call toll-free at 1-866-626-4282. More information about the Trade Act is also available at [www.doleta.gov/tradeact/2002act\\_index.asp](http://www.doleta.gov/tradeact/2002act_index.asp). The Fund Administrator may also be able to assist you with your questions.

**Keep the Fund Informed of Address Changes**

In order to protect your family's rights, you should keep the Fund Administrator informed of any changes in the addresses of your family members. You should also keep a copy, for your records, of any notices that you send to the Fund Administrator.

#### **Consequences of Failing to Elect COBRA**

In considering whether to elect continuation coverage, you should take into account that a failure to continue your group health coverage will affect your future rights under federal law. First, you can lose the right to avoid having pre-existing exclusions applied to you by other group plans if you have more than a 63-day gap in health coverage, and election of continuation coverage may help you prevent such a gap. Second, you will lose the guaranteed right to purchase individual health insurance policies that do not impose these pre-existing condition exclusions if you do not get continuation coverage for the maximum time available to you. Finally, you should take into account that you have special enrollment rights under federal law. You have the right to request special enrollment in another group health plan for which you are otherwise eligible (such as a plan sponsored by your spouse's employer) within 30 days after your group health coverage ends because of the qualifying events listed above. You will also have the same special enrollment right at the end of continuation coverage if you get continuation coverage for the maximum time available to you.

#### **Certificate of Creditable Coverage**

When your coverage ends, the Fund Office will mail you and/or your dependents a Certificate of Creditable Coverage that indicates the period of time that you were covered under the New England Carpenters Health Benefits Fund.

If you become eligible for coverage under another group health plan within 62 days of the date you lose coverage under the New England Carpenters Health Benefits Fund, this certificate may be necessary if your new group health plan has pre-existing condition limitations that apply to you.

The Fund Office will mail this certificate to you shortly after they learn that your coverage has ended. You may request a certificate from the Fund Office within two years from the date your coverage ended. To request a Certificate of Creditable Coverage, contact:

Director and Field Representative  
New England Carpenters Health Benefits Fund  
P.O. Box 7075  
Wilmington, MA 01887  
Phone: (800) 344-1515  
Fax: (978) 657-8724

## LIFE EVENTS

Your benefits are designed to adapt to your needs at different stages of your life. This section describes how your coverage is affected when you experience certain "life events" and what you must do to make sure you get the most from your coverage.

### FAST FACTS:

- You should notify the Fund Office as soon as possible if you experience a life event that may affect your coverage.
- You and/or your dependents may qualify to continue coverage under COBRA in the event of a loss of eligibility, divorce, or your termination or reduction of your work hours.
- If you become disabled, you may be entitled to receive an extension of coverage for up to 12 months.

The following life events may affect your coverage:

Moving to a new address	Entering active military service
Getting married	Becoming disabled
Having a baby	Retiring
Taking family medical leave	Becoming eligible for Medicare
Adopting a child	Death
Getting divorced	

### IF YOU MOVE

If you have a change of address, contact the Fund Office for a change of address form as soon as possible to make sure your records are up to date and to avoid a delay in payment of claims.

### IF YOU GET MARRIED

If you legally marry, your spouse is eligible to receive dependent benefits under the New England Carpenters Health Benefits Fund.

#### What You Need To Do

If you get married, you should provide the Fund Office with the following information:

- A copy of your marriage certificate, available from the town or city hall where you were married;
- Your spouse's date of birth and Social Security number; and
- A copy of your spouse's medical insurance information, if he or she is covered under another group insurance plan.

Once you provide the required information, your spouse is eligible for coverage under the Fund as of the date of your marriage. If you wish to name your spouse as your beneficiary for your life insurance benefit or accidental death and dismemberment benefit, contact the Fund Office for "Change of Beneficiary" form.

If your spouse is covered under another group medical plan, you must report this other coverage to the Fund Office. The amount of benefits payable under this Fund will be coordinated with your spouse's other coverage. Benefits for your spouse under this Fund will be paid after any benefits are payable from your spouse's plan. For more information, see "Coordination of Benefits" on page 54.

**If You Acquire a Child Through Marriage**

Notify the Fund Office if you are planning to cover a stepchild under this Fund. You must provide certain information in order to cover your stepchild:

1. If the natural parents were married, the following is needed:
  - The child's birth certificate;
  - The child's Social Security card;
  - The divorce decree; and
  - A joint tax return showing that the Member claims the child as a dependent.
2. If the natural parents were never married, the following is needed:
  - The child's birth certificate;
  - The child's Social Security card;
  - A joint tax return showing that the Member claims the child as a dependent; and
  - The court order. If no court order exists, you must provide a written statement indicating whether the natural mother has insurance for the child(ren) and whether the natural father has insurance for the child(ren).
3. If one of the natural parents has passed away, the following is needed:
  - The child's birth certificate;
  - The child's Social Security card;
  - A joint tax return showing that the Member claims the child as a dependent; and
  - A copy of the death certificate of the natural parent.

**IF YOU HAVE A BABY**

Once your child is born, notify the Fund Office as soon as possible. You will need to provide certain information in order to have your child covered by this Fund.

**What You Need To Do**

If you have a baby, you should provide the Fund Office with the following information:

- A copy of the baby's birth certificate listing both parents;
- A copy of the child's Social Security card; and
- A copy of your baby's other medical insurance information if he or she is covered under another group insurance plan.

The Health Benefits Fund covers expenses related to maternity, prenatal care and child wellness exams. For information, see pages 30-34.

**IF YOU ADOPT A CHILD**

If you adopt a child, contact the Fund Office. Your child will be covered as of the effective date of the adoption placement as long as you are responsible for health care coverage and your child meets the Fund's definition of a dependent child (see page 8).

**What You Need To Do**

If you need to add a child to your coverage, you must provide the Fund Office with the following information:

- A copy of the child's birth certificate, when it becomes available;
- A copy of the child's Social Security card, when it becomes available;
- A copy of the Adoption Agency paperwork indicating the specific date the child was placed in your home; and
- A copy of the initial adoption paperwork, when it becomes available.

**Legal Guardianship**

If you become a child's Legal Guardian, coverage for the child will be effective as of the date specified on court documents. You must provide the Fund Office with:

- A copy of the child's birth certificate;
- A copy of the child's Social Security card, when available;
- A copy of the court document indicating that you as the Member are the legal guardian of the child.

**Family Medical Leave Act**

If you take leave in certain circumstances such as serious illness, birth of a child, or caring for a seriously ill parent or spouse, your employer may be obligated to continue contributions on your behalf under the Family Medical Leave Act (FMLA). Talk to your employer for details.

**IF YOU DIVORCE**

If you divorce from your spouse, notify the Fund Office as soon as possible. The Plan will cover your ex-spouse as required by the divorce, but under no circumstances will the Plan cover both the ex-spouse and a current spouse.

**What You Need To Do**

If you get legally divorced, you must provide the Fund Office with the following information:

- A copy of your divorce decree; and
- If you have children and you do not have custody, a copy of any Qualified Medical Child Support Order (QMCSO), if applicable.

If your spouse wants to continue coverage, he or she must:

- Contact the Fund Office; and
- Enroll in COBRA Continuation Coverage.

Your former spouse may continue coverage under COBRA for up to 36 months. He or she must notify the Fund Office within 60 days of the day that the divorce becomes final. The Fund Office will then send the COBRA Notice and enrollment information to your former spouse. For more information, see page 11.



Under certain situations, the Fund is required to continue to provide coverage to a divorced spouse of a Member who continues to maintain eligibility and coverage under the Plan. The Fund will only maintain coverage for a former spouse if presented with a court separation or alimony agreement stipulating that the Member is required to provide health coverage for the former spouse. A continuation of benefits under this Plan to a former spouse shall only be maintained until the termination date set forth in the Order or the date the Member or spouse remarries, whichever occurs first. Coverage for the former spouse will terminate when coverage for the Member terminates.

**Qualified Medical Child Support Order (QMCSO)**

A Qualified Medical Child Support Order (QMCSO) is a court order, judgment or decree that recognizes that an alternative recipient may be entitled to benefits under this Fund in the event of a divorce or other family law action. Orders must be submitted to the Fund Office to determine whether the order is a QMCSO under federal law. As required under the Employee Retirement Income Security Act (ERISA), this Fund will recognize a QMCSO that:

- Provides for health coverage to the child(ren) under state domestic relations law (including a community property law); and
- Relates to benefits under this Fund.

Please notify the Fund Office if your situation involves a QMCSO for information about how these orders are handled. Or, you and/or your beneficiary(ies) can obtain, without charge, a copy of the Plan's QMCSO procedures from the Fund Administrator.

**IF YOU ENTER ACTIVE  
MILITARY SERVICE**

If you are on active duty for 31 days or less, you will continue to receive health care coverage for up to 31 days, according to the Uniformed Services Employment and Reemployment Rights Act of 1994 (USERRA).

If you are on duty for more than 31 days, USERRA permits you to continue medical and dental coverage under COBRA (see page 11) for you and your dependents at your own expense for up to 18 months. COBRA will be offered after your active eligibility and coverage runs out. Your dependent(s) may be eligible for health care coverage under TRICARE. The New England Carpenters Health Benefits Fund will coordinate coverage with TRICARE, as explained on page 56.

Coverage under this Fund will not be offered for any illness or injury determined by the Secretary of Veterans Affairs to have incurred in, or been aggravated during, performance of service in the uniformed services. The uniformed services and the Department of Veterans Affairs will provide care for service-connected disabilities.

When you are discharged (not less than honorably) from "service in the uniformed services," your full eligibility will be reinstated on the day you return to the Union Office for work with a Contributing Employer, provided that you return within:

- Ninety (90) days from the date of discharge if the period of service was more than one hundred eighty days; or
- Fourteen (14) days from the date of discharge if the period of service was 31 days or more but less than one hundred eighty days; or



- At the beginning of the first full regularly scheduled working period on the first calendar day following discharge (plus travel time and an additional eight hours) if the period of service was less than thirty-one (31) days.
- You will be granted the same plan of coverage you had when you began active duty.

If you are hospitalized or convalescing from an injury caused by active duty, these time limits are extended up to two years.

#### **What You Need To Do:**

If you are called to military leave, you should:

- Notify your employer and the Fund Office; and
- Make any required self-payments to the Fund Office to continue your coverage.

### **IF YOU BECOME DISABLED**

If you become disabled and cannot work, you may be eligible for a Weekly Accident and Sickness Benefit for up to 26 weeks. See page 51 for more information.

#### **Extension of Coverage for Totally Disabled Members**

If you are totally disabled due to an injury or illness and your coverage under the Health Benefits Fund ends, you will be eligible to extend coverage for up to 12 consecutive months (two coverage periods) from the date your coverage ends. This is a once-per-lifetime benefit. For more information, see page 9.

### **IF YOU BECOME ELIGIBLE FOR MEDICARE**

If you or your covered spouse become eligible for Social Security Retirement Benefits at age 65, you are also eligible for Medicare. Medicare is the federally sponsored health care program consisting of hospital insurance (Part A) and supplementary medical insurance (Part B).

You should enroll in Medicare Parts A and B as soon as you are eligible—three months before your 65th birthday or in certain cases when you become disabled—in order to avoid a gap in coverage.

#### **To Enroll in Medicare:**

- Visit your local Social Security Office
- Call 1-800-MEDICARE (1-800-633-4227), or
- Go to the Medicare website at [www.medicare.gov](http://www.medicare.gov).

If you remain actively employed beyond age 65, you will continue to receive coverage provided you work the required number of hours. You (and your spouse) may elect to participate on a self-pay basis in the group Medicare supplemental plan, provided through the Fund. This supplemental plan is Blue Cross Blue Shield Medex Gold, which includes prescription drug coverage.

For information about how your benefits are paid through the New England Carpenters Health Benefits Fund when you are enrolled in Medicare, see page 55.

**UPON YOUR DEATH**

In the event of your death from any cause while you're covered under Plan I or Plan II, the Fund may provide an extension of health benefits at no cost to your surviving spouse and children for a period of up to three years. This extended coverage will be available if these family members have no other health coverage. Coverage for survivors is provided under the same Plan that you were covered under at the time of your death. See page 10 for more information.

- ✎ Your designated beneficiary must provide a certified copy of the death certificate in order to receive a benefit.

**What Your Beneficiary Needs to Do:**

In the event of your death, your spouse or beneficiary must:

- Notify the Fund Office.
- Provide the Fund Office with an original, certified death certificate, and
- Apply for a life insurance benefit (and AD&D benefit, if applicable).

## YOUR MEDICAL PLAN

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The New England Carpenters Health Benefits Fund provides a comprehensive medical plan with coverage for office visits, hospitalization and surgery, home health care, mental health and substance abuse treatment.

### FAST FACTS:

- If you are covered under Plan I or Plan II, as an active member or dependent, you may visit any physician you'd like, including a physician in or out of the PPO.
- If you are in the Retiree Plan, you must use a physician in the PPO to receive benefits, unless you live outside of a 20-mile radius of a PPO provider.
- Before any hospital admission, you must notify the Fund's managed health care program, for pre-approval.
- Your hours worked determine which Plan you're eligible for. (Refer to page 6 for more information.)

Plans I and II offer a broad range of medical services. You have the freedom to visit any provider you wish, either one that participates in the Plan's Preferred Provider Organization (PPO) network, or an out-of-network provider. Plans I and II offer coverage both in and out-of-network; however, you'll save money for you, your family and for the Fund if you use a provider in the PPO. For a summary of the benefits offered, refer to the Schedule of Benefits on pages 71-77.

The Retiree Plan is a self-pay plan for retirees and their dependents. Coverage is provided when services are obtained only from a network (PPO) provider. For a summary of the benefits offered, refer to the Schedule of Benefits on pages 78-79.

### LIFETIME MAXIMUM PLAN BENEFIT

The Lifetime Maximum amount that the Fund will pay toward eligible expenses per covered individual per lifetime is \$1,000,000 if the Member or eligible dependent is covered under Plan I or the Retiree Plan, or \$500,000 if covered under Plan II.

#### Automatic Reinstatement of Lifetime Maximum Plan Benefit

Each year, the amount of expenses that you or your dependents incur during the previous year is added back to the Lifetime Maximum Plan benefit—up to \$50,000 for Plan I or the Retiree Plan, and up to \$10,000 for Plan II. Note that the total maximum can never exceed \$1,000,000 for Plan I and the Retiree Plan or \$500,000 for Plan II. Automatic restatement can apply if there is a minimum of one benefit cent remaining at the end of the calendar year.

The Lifetime Maximum Plan Benefit is separate among all three plan options per covered individual. For example, if a covered individual switches between Plan II and Plan I and then to the Retiree Plan, each Plan has a separate maximum benefit.

#### Preferred Provider Organization

The Fund contracts with CCN, and pays a monthly fee for access to its network of doctors, hospitals and other health care providers that contract with the CCN PPO.

**Need to Find a PPO provider?**

Visit the CCN website at [www.ccnusa.com](http://www.ccnusa.com) to locate a PPO provider near you.

Using the PPO provides savings and convenience to you, your family and the Fund. When you use a PPO:

- The provider bills the Fund directly; and
- Just one claim form is required each calendar year for each family member.

**Your Share of the Cost**

To help cover health care expenses, you are responsible for sharing some of the cost for services. You are responsible for:

- Copayments;
- The calendar year deductible;
- Your coinsurance; and
- Charges (if any) above the Reasonable and Customary amount if you obtain services outside of the PPO network.

**The Calendar Year Deductible**

The deductible is the amount you (and/or your family) must pay in medical expenses before the Fund will begin to pay benefits. The amount of your calendar year deductible depends on the Plan of Benefits you're covered under, as shown below.

**Calendar Year Deductible**

Plan I	Plan II	Retiree Plan
\$150 individual	\$300 individual	\$250 per person
\$300 family	\$600 family	N/A

!! Any amount you pay toward the deductible under Plan I or Plan II for services rendered in October, November or December of that year is applied to the deductible for the following calendar year. That way, you are saved from having to meet the deductible twice in a short period of time.

**Office Visit Copayment**

If you visit an in-network provider, there is a \$10 copayment due the provider at the time of the visit. Copayments do not count toward meeting your deductible, coinsurance or out-of-pocket maximums.

**Emergency Room Penalty**

If you visit a hospital emergency room for non-urgent care, there is a \$50 penalty.

**Coinsurance**

Once you satisfy the calendar year deductible for all eligible expenses, the Fund may pay a portion of the benefit. The remainder is your share, or coinsurance amount. Refer to the Schedule of Benefits, beginning on page 71, for specific coinsurance information.

**Reasonable and Customary Charges**

A Reasonable and Customary (R&C) charge is the "going rate," as determined by the Plan based on published guidelines, for a particular medical service or supply in a specific geographic area. If your health care provider charges more than the R&C rate for a particular service, you will be responsible for paying that additional amount. For example, if your doctor charges \$500 for a service, but the R&C charge is \$475, you will be responsible for paying \$25 in addition to your coinsurance.

**Out-of-Pocket Maximums**

The Fund has limits on the amount that you must pay out of your own pocket for eligible medical expenses (your coinsurance and deductibles) each year. After you've reached that limit, the Fund will pay 100% of your eligible medical expenses for the remainder of the calendar year, up to the Lifetime Maximum.

**Out-of-Pocket Maximum**

<b>Plan I</b>	<b>Plan II</b>	<b>Retiree Plan</b>
\$1,500 per person	\$3,000 per person	\$3,000 per person

Coinurance for mental health or alcohol/substance abuse inpatient and outpatient services does not apply toward the out-of-pocket maximum per calendar year.

**MANAGED HEALTH CARE PROGRAM — PREAUTHORIZATION**

You or your medical provider must contact Hines & Associates in advance if you are going to be admitted to the hospital for any reason or will receive home health care services or hospice care upon discharge from an inpatient stay. The Hines & Associates provider will contact your doctor and evaluate your proposed treatment needs and medical care standards in your community.

**What Services Require Preauthorization?**

Contact Hines & Associates at 1-800-944-9401 for authorization before you receive any of the following treatments or services:

- Inpatient hospitalization;
- Certain out-patient surgeries;
- Home health care services; or
- Hospice care.

**Preauthorization for Hospitalization**

The managed health care program helps the Health Benefits Fund keep down the cost of a hospital admission and helps you to make better decisions when you need care. This program is mandatory for all eligible Members and dependents under all Plans of Benefits. It is your responsibility to contact Hines & Associates before any inpatient hospitalization. If you do not receive prior authorization for any hospital admission, your hospitalization benefit will be reduced by \$500.

**Precertification Requirement for Outpatient Surgical Procedures**

Hines & Associates must be contacted to Pre-certify the Outpatient Surgical Procedures listed below:

- EVLT (Endovenous Laser Therapy) for Varicose Veins
- Septoplasty
- Blepharoplasty
- Breast Reduction
- Abdominoplasty (Panniculectomy)
- Biopsy
- LeForte Osteotomy
- UPPP (Uvulopalatopharyngoplasty)

The following is an example of the medical information Hines & Associates may request:

- Clinical History
- Office Notes
- Photos

This is only a partial list of procedures that need precertification and medical information Hines & Associates may require. Please contact the Fund office for more information.

**What You Need To Do:**

Contact Hines & Associates by calling 1-800-944-9401 for authorization prior to your inpatient Hospitalization.

Make sure you have the following information available:

- Name and Social Security number of the patient;
- Name and Social Security number of the covered Member if different from the patient;
- Date of proposed admission;
- Name, address and telephone number of the attending physician; and
- Name, address and telephone number of the hospital.

You will be notified in writing of the authorization. If you have not received a written authorization by the day of your admission, call Hines & Associates.

**Emergency Admission Review Procedure**

If you have a medical emergency, you (or a family member) must notify Hines & Associates within 24 hours of your admission. Show your insurance identification card to your doctor and the admissions office of the hospital. For your convenience, Hines & Associates phone number is printed on your card. Failure to notify Hines & Associates will result in a \$500 penalty.

**What's Covered**

The New England Carpenters Health Benefits Fund provides eligible Members and their dependents with a comprehensive plan of benefits. Coverage includes office visits, hospitalization and surgery, wellness benefits, substance abuse and mental health treatment, coverage for prescription drugs, dental care (Plan I only) and vision care. The benefits are described in more detail on the following pages of this book.

For more information about what's covered under your Plan of Benefits, refer to the Schedule of Benefits on pages 71-79.

**What's Not Covered**

A comprehensive listing of the Fund's general exclusions are listed on page 52 and 53.

## **WELLNESS BENEFITS**

### **ANNUAL PHYSICAL EXAMS**

You and your spouse are entitled to one physical exam per calendar year, up to a maximum of \$150 for Plan I, \$75 for Plan II and \$100 for the Retiree Plan.

Flu shots can be considered under this benefit if the available dollars are not exhausted. Any additional charges such as laboratory and/or x-ray charges that exceed the maximum amount the Plan will pay will be your financial responsibility.

### **ANNUAL PAP TESTS AND MAMMOGRAMS**

Annual Pap tests and mammograms are covered as a sickness benefit and are not subject to the maximum for the routine physical exam.

### **WELL-CHILD EXAMS**

#### **Plan I**

Your children are covered for routine well-child exams at 100% of charges after a \$10 copayment from birth up through age five. Your children age six and older are covered at 100% for annual physical exams to a maximum of \$70 per calendar year until they turn 19 (or through age 23 if a full-time student).

#### **Plan II**

Your children through age five only are covered at 100% with a \$10 copayment for annual physical exams when network providers are used. Well-child exams for children aged six or older are not covered under Plan II.

#### **Retiree Plan**

Your children in the Retiree Plan are not covered for well-child exams.

Refer to the Schedule of Benefits on pages 71-79 for more information.



## HOSPITALIZATION AND SURGERY

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The New England Carpenters Health Benefits Fund provides hospitalization and surgery coverage for you and your eligible family members. Your specific coverage depends on your Plan of Benefits and whether you use a hospital and/or a surgeon in the PPO network.

### FAST FACTS:

- All inpatient hospitalization must be precertified prior to any hospital stay. If you do not pre-certify your hospital stay you will have to pay a penalty, and your hospitalization may not be covered.
- Emergency treatment is covered at 100% when you use a PPO Urgent Care Center instead of an emergency room.
- Doctor's charges for maternity care, including pre-natal care and delivery, are covered at 100% of R&C through a PPO provider.

### HOSPITALIZATION

Inpatient and outpatient hospital expenses will be billed to the Fund Office. Covered eligible expenses will be reimbursed according to the chart below, after you've met your deductible. If you are in Plan I or Plan II, you may use any hospital you'd like; however, if you use a hospital in the PPO, your costs may be less. Retiree Plan participants must use a PPO hospital to receive benefits, unless you live more than 20 miles from a PPO hospital.

**What You Need To Do:**  
When you call Hines & Associates, make sure you have the following information available:

- Name or Social Security number of the patient;
- Name or Social Security number of the covered Member, if different from the patient;
- Date of proposed admission.

#### Inpatient Hospitalization

	Plan I	Plan II	Retiree Plan
<b>PPO Network</b>	100% of network charges up to the first \$10,000. Then, 90% after you've met your deductible.	80% of network charges after you've met your deductible.	80% of network charges after you've met your deductible.
<b>Out-of-Network</b>	85% of charges after you've met your deductible.	75% of charges after you've met your deductible.	80% of charges after you've met the deductible, provided you live outside a 20-mile radius from a PPO provider.

☐ Precertify your hospitalization by calling 1-800-944-9401.

#### Mandatory Pre-Hospitalization Review

If you are going to be hospitalized, you or your doctor must call Hines & Associates, the Fund's Health Management provider, within 24 hours to have your hospitalization authorized in advance. If you do not contact Hines & Associates and receive prior authorization for your hospital stay, your benefits will be reduced by \$500 for that claim. See page 27 for more information.

#### Emergency Care

Emergency care is limited to treatment of major illness or injuries requiring urgent attention. Surgery (including but not limited to sutures, casting, cast removal, strapping, removal of foreign bodies) and/or supplies that you may require are subject to the calendar year deductible and provisions of regular plan benefits.

**Emergency Room**

	<b>Plan I</b>	<b>Plan II</b>	<b>Retiree Plan</b>
<b>PPO Network</b>	90% of network charges after you've met your deductible.	80% of network charges after you've met your deductible.	80% of network charges after your deductible. 50% of network charges for non life-threatening emergencies.
<b>Out-of-Network</b>	85% of charges after you've met your deductible.	75% of charges after you've met your deductible.	80% of charges after you've met your deductible. 50% of the out-of-network charges for non life-threatening emergencies provided you live outside a 20-mile radius from a PPO provider.

**!!** You are strongly encouraged not to use a hospital emergency room for urgent care unless there is a life-threatening condition. You will incur a \$50 penalty for any visit to a hospital emergency room for routine urgent care that is not life-threatening.

**Life-Threatening Conditions Include:**

- Abdominal pain
- Accidental injuries
- Acute allergic reactions
- Acute asthma
- Acute gallbladder attack
- Appendicitis
- Cerebral or cardiac spasms
- Coma
- Diabetic coma
- Hypothermia
- Insertion of catheter for acute retention
- Insulin shock and overdose
- Kidney stone
- Maternity complications
- Pneumonitis
- Respiratory distress
- Severe chest pain
- Severe effects of exposure (frostbite, sun or heat stroke)
- Shock
- Spontaneous pneumothorax
- Strangulated hernia
- Stroke
- Sudden loss of vision
- Suspected heart attack
- Thrombosis and/or phlebitis
- Unconsciousness

**SURGEON'S CHARGES**

The chart below shows the amount payable for eligible surgical expenses based on your Plan of Benefits.

<b>Surgery</b>			
	<b>Plan I</b>	<b>Plan II</b>	<b>Retiree Plan</b>
<b>Surgeon's Charges (PPO Network)</b>	100% of fee schedule. Otherwise subject to R&C charges.	100% of fee schedule. Otherwise subject to R&C charges.	100% of fee schedule. Otherwise subject to R&C charges.
<b>Surgeon's Charges (Out-of-Network)</b>	85% of R&C charges for eligible expenses after you've met your deductible.	75% of R&C charges for eligible expenses after you've met your deductible.	80% of R&C charges for eligible expenses after you've met your deductible, provided you live outside a 20-mile radius from a PPO provider.

**!!** Please note that certain charges that are related to surgery, such as facility charges, anesthesia or laboratory charges are not included in the physician's charges for your surgery. For more information, see the Schedule of Benefits on pages 71-79.

**Maternity**

Doctor's charges for maternity care, including pre-natal care and delivery, are covered at 100% of the PPO fee schedule, otherwise subject to R&C charges. Expectant mothers covered under Plan I or II are covered for alpha-fetoprotein and other related pre-natal testing at 100% of the charges when a PPO provider performs the tests. Any laboratory work sent outside the PPO network for processing or analysis will be covered, subject to the deductible, according to your Plan's Schedule of Benefits.

**Voluntary Maternity Early Discharge Benefit**

The early Maternity discharge program is offered to mothers who choose to be discharged within one day after normal vaginal delivery, or three days after a Caesarean section. Those mothers may receive ONE Registered Nurse Home Health Care visit. The hospital must notify Hines & Associates to obtain prior approval for this benefit.

Hines & Associates will recommend an in-network provider, if available. If an in-network provider is used, the benefit for the Home Health visit will be paid at 100% of contract, after your plan deductible is satisfied.

If an out-of-network provider is used, the Home Health visit will be paid at the out-of-network level of your plan benefits.

**Newborns' and Mothers' Health Protection Act of 1996**

Group health plans and health insurance issuers generally may not, under federal (or state) law, restrict benefits for any hospital length of stay in connection with childbirth for the

mother or newborn child to less than 48 hours following a vaginal delivery, or less than 96 hours following a Cesarean section. However, federal law generally does not prohibit the mother's or newborn's attending provider, after consulting with the mother, from discharging the mother or her newborn earlier than 48 hours (or 96 hours as applicable). In any case, plans and issuers may not, under federal law, require that a provider obtain authorization from the plan or issuer for prescribing a length of stay not in excess of 48 hours (or 96 hours).

**Women's Health and Cancer Rights Act of 1998 (WHCRA)**

If you have or are going to have a mastectomy, you may be entitled to certain benefits under the Women's Health and Cancer Rights Act of 1998 (WHCRA). For individuals receiving mastectomy-related benefits, coverage will be provided in a manner determined in consultation with the attending physician and the patient, for:

- All stages of reconstruction of the breast on which the mastectomy was performed;
- Surgery and reconstruction of the other breast to produce a symmetrical appearance;
- Prostheses; and
- Treatment of physical complications of the mastectomy, including lymphedema.

Your physician must contact Hines & Associates at 1-800-944-9401 in advance for pre-approval of these services.

These benefits will be provided subject to the same deductibles and coinsurance applicable to medical and surgical benefits provided under your Plan's Schedule of Benefits. Therefore, the following deductibles and coinsurance apply:

	Plan I	Plan II	Retiree Plan
<b>Calendar Year Deductible</b>	\$150 per person \$300 per family	\$300 per person \$600 per family	\$250 per individual
<b>Surgeon's Expenses (PPO)</b>	100% of PPO fee schedule. Otherwise subject to R&C charges.	100% of PPO fee schedule. Otherwise subject to R&C charges.	100% of PPO fee schedule. Otherwise subject to R&C charges.
<b>Surgeon's Expenses (Out-of-Network)</b>	85% of R&C charges after deductible	75% of R&C charges after deductible	80% of R&C charges after deductible
<b>Hospital Room and Board (PPO)</b>	100% of the first \$10,000, then payable at 90% after deductible	80% after deductible	80% after deductible
<b>Hospital Room and Board (Out-of-Network)</b>	85% after deductible	75% after deductible	80% after deductible
<b>Hospital Physician Expense Benefit (PPO)</b>	90% of charges after deductible	80% of charges after deductible	80% after deductible
<b>Hospital Physician Expense Benefit (Out-of-Network)</b>	85% of R&C charges after deductible	75% of R&C charges after deductible	80% of R&C charges after deductible

If you would like more information on WHCRA benefits, call the Fund Office at (800) 344-1515.

## MENTAL HEALTH AND SUBSTANCE ABUSE

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The Fund provides certain coverage under Plan I, Plan II and the Retiree Plan for treatment of Mental Health and Substance Abuse for you and your eligible dependents.

### Mental Health and Substance Abuse Treatment

	Plan I	Plan II	Retiree Plan
<b>Outpatient Mental Health</b> PPO Network; requires a \$10 copay	100% of network charges to a calendar year maximum of 25 visits per person per calendar year.	100% of network charges to a calendar year maximum of 10 visits per person per calendar year.	100% of network charges to a calendar year maximum of 25 visits per person per calendar year.
<b>Outpatient Mental Health</b> Out-of-Network	50% of R&C charges to a calendar year maximum of 25 visits per person per calendar year, after you've met your deductible.	50% of R&C charges to a calendar year maximum of 10 visits per person per calendar year, after you've met your deductible.	50% of R&C charges up to a calendar year maximum of 25 visits per person, after you've met your deductible, if you live outside a 20-mile radius from a PPO provider.
<b>Inpatient Mental Health</b> PPO Network	90% of network charges to a calendar year maximum of 30 days per person, after you've met your deductible.	80% of network charges to a calendar year maximum of 30 days per person, after you've met your deductible.	80% of network charges to a calendar year maximum of 15 days per person, after you've met your deductible.
<b>Inpatient Mental Health</b> Out-of-Network	85% of charges to a calendar year maximum of 30 days per person, after you've met your deductible.	75% of charges to a calendar year maximum of 30 days per person, after you've met your deductible.	80% of charges to a calendar year maximum of 15 days per person, after you've met your deductible.
<b>Outpatient Substance Abuse</b> PPO Network; requires a \$10 copay	100% of network charges to a calendar year maximum benefit of \$500 per calendar year per person.	100% of network charges to a calendar year maximum benefit of \$500 per calendar year per person.	100% of network charges to a calendar year maximum benefit of \$500 per calendar year per person.
<b>Outpatient Substance Abuse</b> Out-of-Network	85% of R&C charges to a calendar year maximum benefit of \$500 per calendar year per person, after you've met your deductible.	75% of R&C charges to a calendar year maximum benefit of \$500 per calendar year per person, after you've met your deductible.	80% of R&C charges to a calendar year maximum benefit of \$500 per calendar year per person, after you've met your deductible.
<b>Inpatient Substance Abuse (Drug &amp; Alcohol)</b> PPO Network	90% of network charges, after you've met your deductible Maximum of 30 Inpatient Days Per Calendar Year Per Person Maximum of Two (2) LIFETIME Occurrences Per Person	80% of network charges, after you've met your deductible Maximum of 30 Inpatient Days Per Calendar Year Per Person Maximum of Two (2) LIFETIME Occurrences Per Person	80% of network charges, after you've met your deductible Maximum of 15 Inpatient Days Per Calendar Year Per Person Maximum of Two (2) LIFETIME Occurrences Per Person
<b>Inpatient Substance Abuse (Drug &amp; Alcohol)</b> Out-of-Network	85% of charges after you've met your deductible Maximum of 30 Inpatient Days Per Calendar Year Per Person Maximum of Two (2) LIFETIME Occurrences Per Person	75% of charges after you've met your deductible Maximum of 30 Inpatient Days Per Calendar Year Per Person Maximum of Two (2) LIFETIME Occurrences Per Person	80% of charges after you've met your deductible Maximum of 15 Inpatient Days Per Calendar Year Per Person Maximum of Two (2) LIFETIME Occurrences Per Person

### **PREAUTHORIZATION**

If your doctor recommends inpatient care for the treatment of Mental Health or Substance Abuse, you must obtain pre-approval through the Fund's Health Management provider, Hines & Associates, by calling 1-800-944-9401 for authorization before your admission. You will be notified in writing of the authorization. If you have not received a written authorization by the day of your admission, call Hines & Associates.

A person who does not complete the prescribed treatment plan that is established at the beginning of his/her treatment will be responsible for paying the full cost of the treatment.

Payment for the treatment of inpatient substance abuse, whether alcohol or drugs, will be limited to two occurrences in a lifetime.

The Health Fund's utilization review firm, Hines & Associates, along with the Carpenters Assistance Program, will assist the Fund in assuring that our Members receive the highest level of care in the appropriate facilities.

## HOME HEALTH CARE

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Home Health Care helps the Fund to keep down hospital expenses by providing an alternative to inpatient hospital care. Home Health Care can not only decrease the length of a hospital admission but can also, in some cases, eliminate a hospital admission altogether. This service can save the Fund 50% or more on the cost of inpatient care. In addition, Home Health Care provides a sense of security during a time of illness. You or a family member can receive many services at home in familiar surroundings and close to family and friends.

### FAST FACTS:

- A Home Health Care Agency is a licensed organization that provides skilled nursing and other therapeutic services for participants that are recovering from an injury or illness in the comfort of their own home.
- Home Health Care through a PPO provider is covered at 100% after you meet the deductible.
- Help with daily living (custodial care) is covered if provided in your home at the direction of a hospice organization.

The Fund's Managed Health Care provider will arrange for medically necessary home health care through the PPO. To be covered, your doctor must submit a letter of medical necessity to the Fund Office. Benefits for Home Health Care are shown in the chart below.

Home Health Care

	Plan I	Plan II	Retiree Plan
<b>PPO Network</b>	100% of network charges, after you've met your calendar year deductible if care begins within 7 days of discharge from an inpatient stay; otherwise, 90% after deductible.	90% of network charges, after you've met your calendar year deductible if care begins within 7 days of discharge from an inpatient stay; otherwise, 80% after deductible.	100% of network charges, after you've met your calendar year deductible if care begins within 7 days of discharge from an inpatient stay; otherwise, 80% after deductible.
<b>Out-of-Network</b>	90% of R&C charges, after you've met your calendar year deductible if care begins within 7 days of discharge from an inpatient stay; otherwise, 85% after deductible.	80% of R&C charges, after you've met your calendar year deductible if care begins within 7 days of discharge from an inpatient stay; otherwise, 75% after deductible.	80% of R&C charges if you've met your deductible and you live outside a 20-mile radius from a PPO provider if care begins within 7 days of discharge from an inpatient stay.

To be covered, charges by a Home Health Care Agency for care at home must start within seven days of a prior hospital confinement for the same or for a related condition OR in order to prevent a proposed hospital confinement.

**What is a Home Health Aide?**

A home health aide is a person who provides care of a medical or therapeutic nature and reports to and is under the direct supervision of a Home Health Care Agency.

**! NOTE:** Custodial care is covered as part of your hospice care benefits if provided in your home at the direction of a hospice organization.

**What's Covered**

Note that only medically necessary services that are prescribed by the attending physician and under the supervision of the attending physician are covered. The following is a partial list of health services available through a Home Health Care Agency:

- Part-time or intermittent nursing care by a registered nurse or by a licensed practical nurse under the supervision of a registered nurse, if services of a registered nurse are unavailable;
- Part-time or intermittent home health aide services, consisting primarily of patient care of a medical or therapeutic nature by other than a registered or licensed practical nurse;
- Physical therapy, speech therapy, medical social work and nutritional consultations provided by the Home Health Care Agency; and
- Medical supplies, medications prescribed by a physician and laboratory services by or on behalf of the Home Health Care Agency to the extent such items would have been covered if the insured had remained in the hospital. Visits must be medically necessary.

**HOSPICE CARE**

Hospice Care is covered at 100% through the PPO for Plans I and II only. A hospice is a facility that provides care and services for the terminally ill and that:

- Provides 24-hour a day nursing care for the terminally ill person with necessary physical, psychological and spiritual needs, with acute inpatient and outpatient care, home care, bereavement counseling directly or indirectly;
- Has a medical director who is a physician;
- Has an interdisciplinary team that coordinates the care and services it provides and that includes at least one physician, one registered professional nurse and one social worker;
- Maintains central clinical records on all patients; and
- Is licensed or accredited as a hospice if required.



## CARPENTERS ASSISTANCE PROGRAM

The Carpenters Assistance Program (CAP) provides free, confidential assistance for you and your family members when confronting stress, depression, alcoholism, drug abuse, and job or family problems.

### FAST FACTS:

- The Carpenters Assistance Program is available to participants and eligible dependents in Plan I, Plan II and the Retiree Plan.
- When you call, a CAP counselor will assess your situation and set up an appointment for short-term counseling or refer you to the appropriate provider for treatment.
- Treatment you receive through the Carpenters Assistance Program is strictly confidential.
- If you receive a referral for inpatient treatment of mental health or substance abuse, you must contact Hines & Associates, the Fund's Health Management provider, at 1-800-944-9401 for pre-admission certification within 24 hours of your admission.

**How to Contact the CAP**  
Call 1-800-344-1515 extension 1160 to speak confidentially with a counselor or to make an appointment.

- ☛ CAP, in association with the Employee Assistance Program (EAP) service of the Mount Auburn Hospital, provides assistance through a network of facilities throughout the area. Professionals determine an appropriate treatment plan for you and/or your covered dependents. To contact Mount Auburn (EAP), call 617-661-0090 or 1-800-888-5105.

You and your family are eligible for the following benefits:

- Assessment for drug, alcohol, marital, emotional or legal difficulties and/or career problems;
  - Referral to the appropriate facility for the treatment of drug or alcohol dependency (see Mental Health and Substance Abuse on page 35);
  - Diagnostic evaluation and referral to inpatient and/or residential treatment facilities;
  - Full coverage for short-term counseling provided by the EAP services of Mount Auburn Hospital for up to eight one-hour visits per incident;
  - Case management and follow-up services for one year; and
  - Educational seminars, outreach activities and consultation.
- ☛ If you are admitted to a hospital or other facility for emergency care for a mental disorder or for substance abuse treatment, you, a member of your family, your doctor, or the hospital must call Hines & Associates at 1-800-944-9401 within 24 hours of your admission.
- !! Note: Court-ordered or random drug testing is not covered under the Carpenters Assistance Program.

## PRESCRIPTION DRUGS

The prescription drug benefit offers you and your family a convenient and cost-effective way to receive your prescription medication. You may have your prescriptions filled by mail or at a pharmacy. If you use generic drugs, you will save money for yourself and for the Health Benefits Fund.

### FAST FACTS:

- Present your Ullicare Rx/Medco card at a participating pharmacy and make the applicable copayment to receive your prescription drugs.
- You can save time and money by using the mail order program. You can order a 90-day supply of generic prescription drugs for just \$20.
- For retirees, a \$15,000 per individual per calendar year maximum applies.

The chart below shows your copayments for prescription drugs based on whether you receive your prescription medication from a retail pharmacy or through the mail.

Prescription Drugs*			
	Generic	Brand Preferred	Brand Non-Preferred
Retail (34-day supply)	\$10.00	\$20.00	\$30.00
Mail (90-day supply)	\$20.00	\$40.00	\$60.00

\* The calendar year maximum is \$15,000 per individual in the Retiree Plan.

### Generic Drugs

The Health Benefits Fund encourages the use of generic drugs. Generic drugs are a less expensive alternative to brand name drugs. The generic version of any drug contains identical active chemical ingredients and must meet the same manufacturing standards and federal requirements for safety and effectiveness as a brand name drug. Your copayments for generic drugs are lower whether you use a retail pharmacy or order your prescription drugs by mail.

### Brand Preferred

This category of medications consists of brand name and generic medications that are the most commonly used, the most cost efficient and the most therapeutically beneficial in the treatment of common health conditions.

### Brand Non-Preferred

All brand name and generic medications not falling into the above categories.

### How to Get Your Prescription Drugs

When you fill a prescription at a pharmacy, you simply present your Ullicare Rx/Medco card when you request your medication and pay the applicable copayment.

### Mail Order Program

The mail order program is a convenient way for you to receive any medication—especially “maintenance drugs” that you need to take on a regular basis. Because you

know in advance that you will need this medication, it's easy to establish a routine of filling such prescriptions by mail. Through the mail order program, you are eligible to receive medication for up to a 90-day supply. Contact the Fund Office for a mail order form.

#### **What are Maintenance Drugs?**

Maintenance drugs are those that you require on an ongoing basis such as medication for high blood pressure, heart conditions or diabetes.

#### **What's Covered**

Coverage for prescription drugs is provided for the following non-hospital items:

- Legend drugs;
- Injectable insulin and supplies, including hypodermic needles, syringes and test material;
- Compounded medication of which at least one ingredient is a prescription legend drug; or any other drug which, under state law, may only be dispensed upon the written prescription of a physician;
- Oral contraceptives;
- Viagra (6 tablets every 30 days).

#### **What's Not Covered**

No benefits are payable for:

#### **How to Fill a**

#### **Mail Order Prescription**

Obtain a written prescription from your doctor for a 90-day supply of medication. The prescription must include:

- The patient's full name
- The doctor's name, phone number and address
- Exact strength, quantity and dosage; and
- Diagnosis, if required for that drug.
- Call the Fund Office to request a mail order form.

- The difference in charges between a generic drug and brand name drug unless "Dispensed as Written" appears on the prescription;
- Drugs or medicines lawfully obtainable without a prescription order of a physician or dentist except insulin;
- Birth control devices (other than oral contraceptives);
- Levonorgestrel (Norplant);
- Therapeutic devices or appliances and support garments;
- Immunization agents, biological sera, blood or blood plasma;
- Drugs labeled "Caution—limited by federal law to investigational use" or with similar language or experiment drugs even though a charge is made to the person;
- Any charge for the administration of prescription legend drugs or insulin;
- Any medication, legend or not, which is consumed or administered at the place where it is dispensed;
- Medication which is to be taken by or administered to the person in whole or in part while he or she is a patient in a licensed hospital, rest home, sanitarium, extended care facility, convalescent hospital, nursing home or similar institution which operates on its premises, a facility for dispensing pharmaceuticals;
- Refilling of a prescription in excess of the number specified by the physician or dentist or any other refill dispensed after one year from the order of a physician or dentist;
- Prescription drugs that may be properly received without charge under local, state or federal programs, including Workers' Compensation or similar law;

- The following drugs:
  - Aero Chamber (covered under the Medical Plan with a letter of medical necessity);
  - Hepatitis A or B (covered under the Medical Plan with a letter of medical necessity);
  - Rogaine (Minoxidil or Loniten) when prescribed for hair restoration;
  - Retin-A (Tretinoin Cream, Gel, Liquid) except when prescribed by a physician for acne or a skin disorder for an eligible dependent child before age 24 (covered under the medical plan for adults with letter of medical necessity);
  - Smoking deterrent medications;
  - Fertility drugs\* such as, but not limited to:
    - Pergonal (menotropins);
    - Profasi HP (HCG-Human Chorionic Gonadotropin);
    - Pro-Ception;
    - Serophene (Clomiphene Citrate);
    - Clomid (Dienestrol);
    - Lupron;
  - Ephinephrine – primatine mist;
  - Ephedrine sulfate – absolute decongestant;
  - Ferrous sulfate – iron supplement;
  - Elixir terpin hydrate – expectorant;
  - Over the counter vitamins with or without fluoride; and
  - Growth hormones.

\*Certain fertility drugs are covered under the Medical Plan.

## DENTAL CARE

Healthy teeth and gums are an important part of your overall health. That's why the Health Benefits Fund offers comprehensive dental benefits through Delta Dental, the nation's largest dental network. Dental benefits are provided for participants in Plan I only.

### FAST FACTS:

- You do not have to meet a deductible to receive dental care.
- You may visit any dentist you'd like, but you'll save money if you use a provider in the Delta Dental network— "Delta Preferred Option USA Plus."
- There are no claim forms to file if you use a Delta Dental Network provider.
- Dental benefits are available to Plan I participants and their eligible dependents.
- The Plan covers orthodontia, even for adults.

If you are covered for benefits under Plan I, you and your dependents are eligible for dental benefits through Delta Dental. Dentists that participate in the Delta Dental network have agreed to provide services at a pre-negotiated discounted rate. When you visit a Delta Dental provider, show your Delta Dental ID card to receive the discounted rates.

The chart below shows the amount the Plan pays for Dental Care through the Delta Dental network.

Dental Benefits (Plan I only)	Plan Pays
Diagnostic and Preventive (includes cleanings and x-rays)	100% of network charges
Restorative, Oral Surgery, Periodontics, Endodontics, Prosthetic Maintenance and Emergency Dental Care	80% of network charges
Prosthodontics (dentures) and Major Restorative	50% of network charges
Orthodontics	100% of network, up to \$2,000 per person per lifetime

### Out-of-Network Benefits

If you do not use a Delta Dental provider, you will be billed for any amount that your out-of-network dentist charges that is more than the pre-negotiated Delta Dental network charge.

### Maximum Benefits

A \$1,500 calendar year maximum dental benefit applies to each covered person for dental services per calendar year. The lifetime maximum benefit for orthodontia is \$2,000 per covered person. There's no age limit for orthodontia.

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**Covered Dental Surgical Services**

The following surgical procedures are covered under the New England Carpenters Health Benefits Fund:

**Questions about  
What's Covered?**

Contact Delta Dental  
Customer Service at  
1-800-872-0500 for  
information about  
limitations or exclusions  
that may apply to a  
particular procedure.

- Surgical removal of unerupted teeth or impacted teeth when imbedded in the bone or soft tissue
  - Soft tissue impaction
  - Partial bony impaction
  - Complete bony impaction
- Extraction of seven or more permanent teeth
- The excision of a benign or cancerous growth other than a radicular cyst
- Radicular cysts involving the roots of three or more teeth
- Gingivectomies involving two or more gum quadrants
- Gingival flap
- Mucogingival surgery
- Osseous surgery
- Osseous graft
- Soft tissue graft
- Apicoectomy

## VISION CARE

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### FAST FACTS:

- You and your spouse may receive an eye exam and a pair of glasses or contacts\* once every 24 months from the Carpenters Vision Center or from a Davis Vision provider. Your dependent children are eligible for an eye exam and a pair of glasses or contacts once every 12 months.
- The Optional Vision Benefit may also be available to you, allowing you to visit a vision care specialist of your choice and receive partial reimbursement for examinations and glasses.

Routine vision examinations are essential for maintaining healthy eyes and good vision. Vision benefits are provided under Plans I, II and the Retiree Plan and for Members and their spouses who are retired and are collecting a pension from the Carpenters Union and are current in their monthly dues. Also eligible are spouses of deceased pensioned Members who continue to collect the Member's pension after their death provided the Member was current with dues at the time of his or her death.

#### The Plan provides:

- For adults – routine eye exam and glasses once every two years; and
- For children – (up to age 19 or 24 if full-time students) routine eye exam and glasses once every year.

"Glasses" means one pair of bifocals or two pairs of single-vision glasses, one for distance and one for close-up. Special lens materials and coatings that are not covered under the vision benefit are available for a reasonable copayment through the Vision Center and Davis Network.

**!! Note:** When using the Davis Network, you must obtain your examination and glasses at the same time and from one provider.

\*You also have the option of choosing contact lenses instead of eyeglasses at the Vision Center or through a Davis Vision Network Provider, with a copayment. The contact lens benefit guidelines are as follows:-

- New wearers, either new to the doctor or first-time obtaining contacts — routine eye examination, a comprehensive fitting and two standard lenses or two boxes of either disposable lenses or planned replacement lenses; and
- Existing wearers — routine eye examination, a reassessment fitting and two standard lenses or two boxes of planned replacement lenses or four boxes of disposable lenses.

**Questions about  
Vision Coverage**

Call the Carpenter Vision Center (617) 782-0100 or the Carpenters Health Benefits Fund Office if you have questions (1-800-344-1515).

The contact lens benefit is not available through the Optional Vision Benefit explained below.

You have three alternatives for receiving vision benefits:

- **Carpenter Vision Center** — owned and operated under the New England Carpenters Health Benefits Fund. It offers complete eye examinations and the largest selection of frames available under the Plan. Optical services that aren't provided under the Plan are available at a discounted rate through the Vision Center. The Vision Center is at 250 Everett St., Allston, MA, and offers afternoon, evening and Saturday appointments. Call (617) 782-0100 for an appointment.

- **Davis Vision Program**—a network of private doctors under contract to provide routine eye exams and eyeglasses or contact lenses. There is a select group of frames available under the Davis Vision Plan. Network doctors are located throughout New England. To find a convenient doctor, call 1-800-999-5431 or visit their website at [www.davisvision.com](http://www.davisvision.com).

Be sure to choose a full-service doctor who can provide both the exam and eyeglasses or contact lenses. When you make your appointment and at the time of your visit, tell the staff you are in the Davis Vision program. If you are retired, you must contact the Carpenter Vision Center (617-782-0100) before contacting Davis Vision.

- **Optional Vision Benefit** — allows you to see any eye doctor you choose and receive a partial reimbursement. This option is available only to members of Plan I or Plan II or members of Local 1996 who live in Maine, Vermont or Northern New Hampshire.

Reimbursement is as follows, regardless of the fee the provider charges:

- Eye exam (routine) — \$50
- Frames (one pair only) — \$40
- Eyeglass lenses (one pair only) — \$60
- Contact lenses — no reimbursement

The following Plan participants must use either the Carpenters Vision Center or a Davis Vision Network Provider:

- Retirees covered under the Retiree Plan.
- Retired members (and their spouses) who are collecting a pension from the Carpenters Pension Plan and are current in their dues.\*
- A surviving spouse who is receiving the Pension of a retired Member who was current in his or her dues at the time of his or her death.\*

\*Members in these categories must contact the Vision Center at 617-782-0100 before utilizing their vision benefit.

**!! The PPO Network ophthalmologists are not part of the vision care benefit.**



## LIFE INSURANCE

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Your designated beneficiary will be eligible for a life insurance benefit from this Fund if you die from any cause while you're an active member and you're covered by the New England Carpenters Health Benefits Fund.

### FAST FACTS:

- Your designated beneficiary will receive a lump sum benefit if you die while you are an active member covered by this Fund.
- Your beneficiary must provide the Fund Office with a certified copy of your death certificate in order to receive a benefit.
- If your current legal spouse dies while you are an active member covered by this Fund, you will be eligible for a lump sum benefit of \$2,000.

The chart below shows the lump sum that is payable to your designated beneficiary upon your death.

Life Insurance			
	Plan I	Plan II	Retiree Plan
Benefit	\$20,000	\$10,000	No Benefit

**Keep Your Beneficiary Information Up-To-Date**  
Contact the Fund Office if you'd like to change your beneficiary if you get married, have a child or get divorced.

### Naming a Beneficiary

• You may name anyone you wish to be your beneficiary and you may change this designation at any time. To change your beneficiary, call the Fund Office for the appropriate form. You do not need to get your beneficiary's consent to make this change. Your change will be effective when the Fund Office receives your completed form.

!! Your beneficiary designation must be on file at the Fund Office at the time of your death to be valid.

If you do not have a designated beneficiary form on file at the Fund Office at the time of your death, or if your designated beneficiary does not survive you, your life insurance benefit will be paid to your estate.

### COVERAGE FOR YOUR SPOUSE

The Fund also provides a life insurance benefit for your spouse. If your current legal spouse dies from any cause while covered under the New England Carpenters Health Benefits Fund, you, as the Member, will be eligible for a lump sum benefit of \$2,000. Note that ex-spouses are not eligible for this benefit.

**What is Total and Permanent Disability?**

The Health Benefits Fund considers you totally and permanently disabled if you are not working at any job for wage or profit, and you are unable to work in any job that is reasonably suited to you by your education, training or experience due to an illness or injury.

**Continuing Coverage If You Become Disabled**

- If you become totally and permanently disabled while you're covered under the Health Benefits Fund, your life insurance benefit will be continued at no cost to you unless you recover from your disability or attain age 65. You must complete and file an application for total and permanent disability with the Fund Office within one year of the date you become disabled and prior to your 60th birthday. The Fund Office will require proof of your continued disability to keep your life insurance in force. Contact the Fund Office to request an application.

**IF YOUR COVERAGE ENDS**

**Extended Benefits**

If you die within 31 days from the date your coverage under the New England Carpenters Health Benefits Fund ends, the full amount of life insurance will be payable to your beneficiary.

**Converting Your Coverage**

- You may convert your life insurance to an individual policy if your coverage under the Health Benefits Fund ends. To apply, contact the Fund Office for an application for conversion through the Hartford Life Insurance Company within 31 days of the date your coverage ends.

## ACCIDENTAL DEATH AND DISMEMBERMENT <sup>49</sup>

Accidental Death and Dismemberment (AD&D) Insurance provides a benefit for Plan I and II Participants for accidental loss of life, limbs or eyesight while you are covered by the New England Carpenters Health Benefits Fund.

### FAST FACTS:

- This benefit is available for the Member only; dependents are not covered under the AD&D benefit.
- The AD&D benefit is payable in addition to and separate from the life insurance benefit.
- Benefits are payable if the loss is a direct result of any injury caused by an accident.

The chart below shows the amount that is payable to you in the case of accidental dismemberment. In the event of your death, the benefit is payable to your designated beneficiary.

**Accidental Death and Dismemberment**

	Plan I	Plan II	Retiree Plan
Loss of Life or loss of movement of both upper and lower limbs (quadriplegia)	\$20,000	\$10,000	No benefit.
Loss of movement of three limbs (triplegia) or loss of movement of both lower limbs (paraplegia)	\$15,000	\$7,500	No benefit.
Loss of a hand, a foot, an eye, speech or hearing. Loss of movement of both upper and lower limbs on one side of the body (hemiplegia)	\$10,000	\$5,000	No benefit.
Loss of thumb and index finger on either hand or loss of movement of one limb (uniplegia)	\$5,000	\$2,500	No benefit.
More than one of the above resulting from one accident	\$20,000 or the sum of the benefits payable for each loss, whichever is less.	\$10,000 or the sum of the benefits payable for each loss, whichever is less.	No benefit.

Loss means the following:

- Loss of a hand or foot means that it is completely cut off at or above the wrist or ankle joint.
- Loss of an eye means that sight in the eye is completely lost and cannot be recovered or restored.
- Loss of speech or hearing means that speech or hearing is lost entirely and the loss cannot be recovered or restored. Hearing must be lost in both ears.
- Loss of movement of limbs means that the movement is completely lost and irreversible.
- Loss of thumb and index finger means actual severance through or above the metacarpophalangeal joints.

### **SEATBELT BENEFIT**

If you are properly wearing a seatbelt (as verified on the police report) at the time of an automobile accident and you suffer a loss that is payable under the AD&D benefit, you may be eligible for a "seatbelt benefit." To be eligible, you must be a passenger riding in an automobile or the licensed operator of the automobile that is involved in the accident. For Plan I, the seatbelt benefit is \$2,000. For Plan II, the seatbelt benefit is \$1,000. There is no seatbelt benefit for members in the Retiree Plan.

#### **What's Not Covered**

The Fund will not pay an AD&D benefit for death or any loss resulting from or caused directly, wholly or partly by:

- Sickness;
- Disease;
- Medical treatment for sickness or disease;
- Any infection, except a pus-forming infection of an accidental cut or wound;
- War or any act of war, whether war is declared or not;
- Any injury received while in any armed service of a country that is at war or engaged in armed conflict;
- Any intentionally self-inflicted injury, suicide, or suicide attempts, whether sane or insane;
- The injured person's intoxication. Intoxication means that blood alcohol content or the results of other means of testing blood alcohol level meet or exceed the legal presumption of intoxication under the law of the state where the accident took place;
- Participation in the commission of a felony; or
- Taking drugs, sedatives, narcotics, barbituates, amphetamines, or hallucinogens unless prescribed for or administered by a licensed physician.

## WEEKLY ACCIDENT AND SICKNESS

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If you become totally disabled and cannot work due to a non-work related injury or illness, you are eligible for a weekly accident and sickness benefit through the New England Carpenters Health Benefits Fund. This benefit is only available to Members in Plan I with worked hours.

### FAST FACTS:

- If you are an eligible Plan I Member and you become disabled while covered under Plan I, you may receive a weekly benefit of \$250 from the Health Benefits Fund for up to 26 weeks.
- The Weekly Accident and Sickness benefit is only available to you while you are under the care of a physician.
- If you are receiving a benefit under Workers' Compensation or unemployment benefit, Occupational Disease Law or similar legislation, you are not eligible for the Weekly Accident and Sickness benefit.

### Please Note

- Payments you receive from the weekly accident and sickness benefit are considered taxable income and must be reported on your federal income tax return. The Fund Office will withhold state and federal income taxes.
- No Social Security (FICA) tax is deducted from your payment. The Fund pays this tax for you.
- You are not eligible for this benefit if you are using Banked Hours to maintain your eligibility.
- For information about filing weekly accident and sickness claims, see page 63.
- If your disability is related to a motor vehicle accident, the Fund does not pay until the benefit from the automobile insurance has been exhausted.
- If your disability is due to an injury but you do not stop working at the time of the injury, the disability is considered an illness and the waiting period applies.
- It is your responsibility to provide updates of your condition to the Fund Office.

### Payment of Benefits

Your benefit of \$250 per week will begin on the first day of the disability if it is due to an accident or the eighth day of the disability if it is due to an illness. Payment will continue during your disability for a maximum of 26 weeks for any one continuous period of disability due to the same or related cause or causes.

When Benefits Begin	Day 1 (Accident)	Day 8 (Illness)
Maximum Benefit	26 Weeks	26 weeks

Successive periods of disability that are separated by less than two weeks of continuous active covered employment are considered one period of disability. If you suffer another disability due to a different and unrelated cause, you must return to active work for a period of more than two weeks to receive a benefit for another period of disability.

**!!** It is not necessary for you to be confined to your home in order to collect a weekly accident and sickness benefit, but you must be under the care of a legally qualified physician licensed to practice medicine.

### Pregnancy-Related Disability

If you are totally disabled and medically unable to work because of pregnancy, childbirth or miscarriage, your weekly accident and sickness benefit is payable from the eighth day of disability on the same basis as any other illness.

### If You're Injured on the Job

If you become disabled due to a work-related illness or injury, you may be eligible for a Workers' Compensation benefit. Contact your employer or Local for information on how to apply for benefits.

## GENERAL EXCLUSIONS

The following is a partial list of plan exclusions for Plan I, II and the Retiree Plan. You may call the Fund Office to request specific information as to whether or not a service or supply is a covered expense. The Plan excludes expenses or charges:

- For services or supplies not recommended by a physician or surgeon or not medically necessary in treating the injury or illness;
- That are in excess of Reasonable and Customary (R&C) charges;
- For medical care or treatment and services or supplies for charges that are made by a nursing home, rest home, convalescent home or similar establishment;
- For services or supplies that are:
  - Not provided in accordance with generally accepted professional medical standards; or
  - For experimental or investigational treatment;
- Custodial care, when not provided in your home at the direction of a hospice care organization;
- That result from cosmetic or reconstructive surgery except:
  - When surgery is performed on an eligible dependent child because of a congenital disease or anomaly that has resulted in a functional defect as determined by his or her attending physician or surgeon; or
  - In the case of an accidental bodily injury;
- In connection with dental work, x-rays or surgery (unless part of the dental benefits for Plan I participants), except expenses for services that are required for correction of damage caused by an accidental injury to a sound and natural tooth sustained by an eligible person, or for tumors or cysts of an eligible person;
- Under Plan I and Plan II Temporomandibular Joint Disorders (TMJ) are excluded for appliances and services, supplies or procedures to increase the height of teeth (increase vertical dimension or restore occlusion) except for (1) disorders caused by or result in a specific medical condition, such as degenerative arthritis and jaw fractures or dislocations. The medical condition must be proven to exist by means of diagnostic x-ray tests or other generally accepted diagnostic procedures; and a mandibular orthopedic repositioning appliance (MORA);
- Temporomandibular Joint Disorders (TMJ) for Retirees;
- Early Intervention Services;
- Made by a Veterans' Administration Hospital or by a physician employed by a Veterans' Administration Hospital if the disability is service related, except as mandated by law;
- That the member is not legally required to pay or that is for medical care furnished without charge, paid for or reimbursable by or through a government agency or county, except where specifically prohibited by applicable statute;
- For special home construction to accommodate a disabled person;
- For medical or surgical treatment of obesity, including but not limited to, gastric restrictive procedures, intestinal bypass and reversal procedures, weight loss programs, dietary instructions, and any complications thereof;

- For medical or surgical treatment of severe underweight, including, but not limited to high calorie and/or high protein food supplements, other food or nutritional supplements, or nutritional counseling, except in conjunction with medically necessary treatment of anorexia, bulimia or acute starvation. Severe underweight means a weight more than 25 percent under normal body weight for the patient's age, sex, height and body frame based on weight tables generally used by physicians to determine normal body weight;
  - For memberships in or visits to health clubs, exercise programs, gymnasiums, and/or any other facility for physical fitness programs;
  - For sterilization reversals;
  - For failure to appear for an appointment as scheduled, for completion of claim forms, attorneys' reports or late stay charges;
  - For injury, illness or dental treatment for which an eligible person has received or is entitled to receive benefits under a Workers' Compensation or Occupational Disease Law or that arises out of or in the course of any occupation or employment;
  - For any loss, expense or charge resulting from an eligible person's participation in the commission of a felony;
  - For any loss, expense or charge resulting from an act of declared or undeclared war, armed aggression or act of terrorism;
  - For any loss, expense or charge incurred while an eligible person is on active duty or in training in the Armed Forces, National Guard or Reserves of any state or country;
  - For supplies or equipment for personal hygiene, comfort or convenience such as air conditioning, humidifier, physical fitness and exercise equipment, tanning bed or water bed;
  - For court-ordered or random drug testing;
  - For Infertility Treatment under the Retiree Plan;
  - For acupuncture unless rendered by an M.D. (Medical Doctor);
  - For services rendered when not an eligible participant; and
  - Claims not received in the Fund Office within 12 months from date of service.
- ☛ Contact the Fund Office at (800) 344-1515 for specific information about whether or not a service or supply is a covered expense.

## COORDINATION OF BENEFITS

Members of a family are often covered under more than one group health plan, which could result in duplication of health coverage. To avoid this, the health care benefits provided by this Fund are coordinated with similar benefits payable under other plans.

### FAST FACTS:

- You must report any duplicate group health coverage for yourself and/or your dependents on any claim you submit to the Fund Office.
- Benefits under this Fund are coordinated with HMO, PPO, Medicare or other group health care coverage.

Under the Coordination of Benefits provision, if you are covered under any other group health plan, the total payment you receive from all programs may not be more than 100% of the "allowable expenses." Allowable expenses are the necessary and reasonable expenses for treatment or supplies covered by the primary plan that you are covered under.

### Methods of Coordination

The plan under which benefits are payable first is the primary plan. All other plans are called secondary plans. The following rules determine which plan's benefits are payable first and follow the National Association of Insurance Commissioner's Model Rules:

- A plan that does not contain a Coordination of Benefits provision is always primary.
- A plan that covers you as a Member is primary.
- If you are covered as a Member under two plans, the plan that has covered you for a longer period is primary.
- A plan that covers you as an active Member pays before a plan which covers you as a laid-off Member or retiree.

### Rule 2: Dependent Child Covered Under More Than One Plan

- A. If the parents of a child are married or are living together, then the plan that covers the parent whose Birthday falls earlier in the calendar year pays first; and the plan that covers the parent whose Birthday falls later in the calendar year pays second. If the parents are not living together but a court decree awards joint custody to both parents without specifying that one parent has the responsibility to provide health care coverage for the child, this rule also applies.
- B. If both parents have the same Birthday, the plan that has covered one of the parents for a longer period of time pays first; and the plan that has covered the other parent for the shorter period of time pays second.
- C. The word "Birthday" refers only to the month and day in a calendar year; not the year in which the person was born.
- D. If the specific terms of a court decree state that one parent is responsible for the child's health care expenses or health care coverage, and the plan of that parent has actual knowledge of the terms of that court decree, that plan pays first. If the parent with financial responsibility has no coverage for the child's health care services or expenses, but that parent's current spouse does, the plan of the spouse of the parent with financial responsibility pays first. However, this provision does not apply during



any Plan Year during which any benefits were actually paid or provided before the plan had actual knowledge of the specific terms of that court decree. 55 |

- E. If the parents are divorced, separated or not living together (regardless of whether they were ever married), and there is no court decree allocating responsibility for the child's health care services or expenses, the order of benefit determination among the plans of the parents and their spouses (if any) is:
1. The plan of the custodial parent pays first; and
  2. The plan of the spouse of the custodial parent pays second; and
  3. The plan of the non-custodial parent pays third; and
  4. The plan of the spouse of the non-custodial parent pays last.

**Coordination of Benefits with Health Maintenance Organizations (HMOs),**

**Preferred Provider Organizations (PPOs) and Similar Organizations**

If you or your dependents are covered by an HMO, a PPO, or a similar health care organization and that group health plan is primary, you must utilize all health care alternatives available to you through the other provider(s) before this Fund will honor any claim for benefits. Also, if a member or his/her dependents violates the provisions of the HMO, such as neglecting to use that plan's facilities or following managed care or precertification provisions, no benefits will be payable under this Plan.

**Coordination of Benefits with Medicare**

When you reach age 65 or if you become disabled, you are eligible for hospital insurance benefits ("Part A") and supplementary medical insurance ("Part B") under Medicare. The chart below illustrates how your benefits are paid at that time.

Type of Plan Participant	Primary Plan	Secondary Plan
Retiree or dependent who is Medicare-eligible (and unemployed) unless you are covered under work hours, then it is reversed	Medicare	This Fund
Retiree who is not Medicare eligible	This Fund	N/A
Active Member and/or dependent who is Medicare eligible	This Fund	Medicare
Disabled Active Member	This Fund	Medicare

**To Enroll in Medicare...**

- Visit your local Social Security Office,
- Call 1-800-MEDICARE (1-800-633-4227), or
- Log on to [www.medicare.gov](http://www.medicare.gov).

**Coverage for Disabled Members or Members' Disabled Dependents with End-Stage Renal Disease (ESRD)**

If you are actively employed and you or any of your covered dependents become entitled to Medicare because of end-stage renal disease (ESRD), this Plan pays first and Medicare pays second for 30 months starting the earlier of:

- The month in which Medicare ESRD coverage begins; or
- The first month in which the individual receives a kidney transplant.

Then, starting with the 31st month, Medicare pays first and this Plan pays second.

Any covered charges incurred by such disabled individual should be submitted to this Plan for payment. Afterward, any unpaid balance should be submitted to Medicare, for their consideration.

**Enrolling in Medicare**

You must enroll in Medicare Parts A and B as soon as you are eligible—three months before your 65th birthday or in certain cases when you become disabled—in order to avoid a gap in coverage.

**TRICARE Military Coverage**

If you and/or your family are covered by both this Fund and TRICARE, the coordination of benefits depends on whether you are called up to active duty for more than 30 days and whether your family continues coverage under this Plan. If you are on active duty for more than 30 days, TRICARE will be primary and this Plan will be secondary. However, if your eligible dependents elect COBRA and continue benefits under this Plan, this Plan would be primary and TRICARE would be secondary for them.

**Motor Vehicle No-Fault Coverage Required by Law**

If you are covered by both this Fund and any motor vehicle no-fault coverage that is required by law, the motor vehicle no-fault coverage pays first, and this Fund pays second.

**Workers' Compensation**

This Fund does NOT provide benefits if the medical expenses are covered by Workers' Compensation or Occupational Disease Law.

**REIMBURSEMENT AND SUBROGATION**

You or one of your eligible dependents may incur medical expenses in a situation where a third party—for example, Workers' Compensation or an auto insurance carrier— may be held responsible for their payment. In this case, the Fund has all rights of recovery that you or your dependents would have, including the right to bring suit in your name.

You must cooperate with the Fund to secure the recovery of the payment, and you must do nothing before or after payment by the Fund to prejudice its rights. If you recover from the third party or its insurer, you must reimburse the Fund for expenses that it has paid.

When you and/or your eligible dependents incur medical expenses where a third party may be held responsible for payment you must:

- Notify the Fund Office
- Execute a Subrogation and reimbursement agreement

The subrogation and reimbursement agreement must be executed by you and/or your covered dependent, and received by the Fund Office within 90 days from the date of the incident and in no event later than 12 months from the date of the incident.

The amount of reimbursement due to the Fund is based on the following schedule:

Total Recovery	Fund's Share of Recovery
1. Equal or less than benefits	50% of the benefits
2. Greater than one, but less than twice benefits	65% of the benefits
3. Greater than two, but less than three times benefits	75% of the benefits
4. Greater than three, but less than four times benefits	85% of the benefits
5. Greater than four times	100% of the benefits

In no event shall the Fund's share of recovery be greater than 50% of the total recovery following the deduction of the participant's reasonable attorney's fees (not to exceed 33% of the total recovery).

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Before paying benefits for expenses that may be the responsibility of a third party, you and/or your dependents will be required to sign an agreement affirming the obligation of you and your dependents to reimburse the Fund from the proceeds of any recovery. The Fund may withhold payments on any claim until a reimbursement agreement is executed. Your obligation to reimburse the Fund, however, is not dependent on whether you sign a reimbursement agreement. By accepting the payment of benefits, you and your dependents agree to the Fund's subrogation and reimbursement policies.

You and/or your eligible dependent must execute the reimbursement agreement and submit it for receipt by the Fund Office within 90 days of the date of the accident or injury. If it is not reasonably possible to submit the executed reimbursement agreement within 90 days, it must be received by the Fund Office as soon as reasonably possible but in no event later than one year from the date of the accident or injury. If you fail to comply with this obligation to sign and submit the reimbursement agreement within the deadline, the Fund will deny claims relating to the accident or injury.

If you receive payment from a third party under any circumstances, you must reimburse the Fund in accordance with the schedule above from the proceeds. Reimbursement is mandatory regardless of whether:

- a claim was ever asserted for the amount received.
- the proceeds were paid by way of settlement, judgment, arbitration award or otherwise.
- you feel that you were "made whole" for your losses by recovery.
- the amount received is characterized as attributable to medical expenses, lost income, pain and suffering, loss of consortium or otherwise.
- part of the recovery is received by family members other than the primary injured party such as on a loss of consortium.

The Fund has an equitable interest and lien in the amount that you receive, and you, your dependents, and those acting on your behalf are under obligation to keep the amount received in a separate segregated account until your obligations to the Fund are satisfied and all disputes concerning those obligations are settled. The Fund may enforce this obligation by seeking equitable relief in court.

In the event that the participant or dependent submits additional claims for benefits following settlement of a liability claim and reimbursement to the Fund, the Fund will withhold future benefits, but only to the extent that the additional benefits would have been reimbursable under the formula had the settlement occurred later.

If you or your dependents do not reimburse the Fund after receiving payment from a third party, the Fund may institute legal and/or equitable action in court. In such event, you will be responsible for all the costs and attorney's fees associated with that court proceeding, and will be obligated to pay all interest on all amounts owed from the date they were due. If you or a dependent fails to reimburse the Fund, the Fund may withhold payment of future benefits from you as well as all of your dependents up to the amount due plus interest.

## FILING YOUR CLAIMS

A claim for benefits is a request for Plan benefits made in accordance with the Plan's reasonable claims procedures. In order to file a claim for benefits offered under this Plan, you must submit a completed claim form unless your hospital, doctor or other health care provider uses a standard billing form, such as a UB 92 or HCFA 1500, and files it directly with the Fund on your behalf.

General inquiries about the Plan's provisions that are unrelated to any specific benefit claim or requests to add or improve the Plan's benefits will not be treated as a claim for benefits. In addition, a request for pre-approval of a benefit that does not require prior approval by the Plan is not a claim for benefits.

All of the following information must be completed on the claim form that you get from your provider(s) in order for your request for benefits to be a claim, and for the Fund Office to be able to decide your claim.

- Member's name and Social Security number
- Member's address
- Member's date of birth
- Member's marital status
- Coordination of benefits information
- Spouse's name and Social Security number (if applicable)
- Spouse's date of birth and employment status (if applicable)
- Name, address and telephone number for spouse's employer
- Patient name and address (if different from Member)
- Patient's relationship to insured
- Patient date of birth
- Patient's sex
- Patient's student status
- Was condition related to patient's employment, or accident
- Date(s) of service
- Date patient able to return to work
- Date of total/partial disability
- Name of referring physician
- Hospitalization dates, if applicable
- CPT-4 (the code for physician services and other health care services found in the *Current Procedural Terminology, Fourth Edition* or later, as maintained and distributed by the American Medical Association)
- ICD-9 (the diagnosis code found in the *International Classification of Diseases, 9th Edition* or later, *Clinical Modification* as maintained and distributed by the U.S. Department of Health and Human Services)
- Billed charge, amount paid and balance due
- Signature of service provider
- Federal taxpayer identification number (TIN) of the provider
- Provider billing name and address

Most accepted standard claim forms contain an assignment of benefits agreement, in the event you wish to assign your hospital or surgical benefits directly to the hospital or doctor. Upon receipt of the assignment agreement, the Fund Office will directly pay these benefits to your health care provider. Please remember that any CCN provider will be paid directly by the Fund. You are only responsible for the copayment amount at the time of the service and any coinsurance and deductible, depending on the benefit.

### **WHEN CLAIMS MUST BE FILED**

Claims should be filed within 90 days from the date the charges were incurred.

Failure to file claims within the time required shall not invalidate or reduce any claim if it was not reasonably possible to file the claim within such time. However, in that case, the claim must be submitted as soon as reasonably possible and in no event later than one year from the date the charges were incurred.

When you and/or your eligible dependents incur charges in circumstances where a third party may be liable, you and/or your eligible dependent must:

- Notify the Fund Office.
- Execute and return a reimbursement agreement within 90 days of the accident or injury. (See section of this book on Reimbursement and Subrogation).

### **WHEN A CLAIM IS CONSIDERED RECEIVED BY THE HEALTH BENEFITS FUND**

#### **Post-Service Claims**

A post-service claim for benefits (as defined on page 62) is considered received by the Fund as follows:

#### **For Medical, Hospital, and Accident and Sickness (Disability) Claims**

- On the first business day when the claim is received by U.S. mail or hand-delivered to the Fund Office at the following address:

New England Carpenters Health Benefits Fund  
350 Fordham Road  
Wilmington, MA 01887  
Phone: (800) 344-1515  
Fax: (978) 657-8724

- It is submitted electronically by your provider and received by the Health and Welfare Fund.

#### **For Dental Claims**

- On the first business day when the claim is received by U.S. mail by Delta Dental at the following address:

Delta Dental Plan of Massachusetts  
P.O. Box 9695  
Boston, MA 02114

- The claim is submitted electronically by your provider and received by Delta Dental.

#### **For Vision Claims**

- On the first business day when the claim is received by U.S. mail by Davis Vision at the following address:

Davis Vision  
159 Express St.  
Plainview, NY 11803

- The claim is submitted electronically by your provider and received by Davis Vision.

**URGENT, PRE-SERVICE AND CONCURRENT CLAIMS**

Urgent, pre-service and concurrent claims (as defined on pages 60-62) are generally requests for preauthorization or precertification of a treatment or hospital stay. An urgent, pre-service or concurrent claim is considered received when a telephone call is made by you or your provider to Hines & Associates at 1-800-944-9401, or your provider electronically contacts the Hines & Associates requesting precertification.

**PRESCRIPTION DRUG CLAIMS**

Ullicare Rx/Medco provides drug preauthorizations for specified drugs. For a complete listing of these drugs, call (800) 818-6602.

When you present a prescription to a pharmacy to be filled under the terms of this Plan, that request is not a "claim" under these procedures. However, if your request for a prescription is denied, in whole or in part, you may file a claim and appeal regarding the denial by using these procedures.

**CLAIMS COMMUNICATIONS**

All claims communications will be addressed to and sent to the Member unless the patient makes a written request to the Health Benefits Fund Office specifically requesting that any claims communications be sent under the patient's name and/or to a different address.

**Authorized Representatives**

An authorized representative, such as your spouse, may complete the claim form for you if you are unable to complete the form yourself and have designated an individual to act on your behalf. A form can be obtained from the Fund Office to designate an authorized representative. The Plan may request additional information to verify that this person is authorized to act on your behalf. A health care professional with knowledge of your medical condition may act as an authorized representative in connection with an Urgent Care Claim (defined below) without you having to complete the special authorization form.

**COMPREHENSIVE MEDICAL BENEFITS CLAIMS**

The claims procedures for comprehensive medical benefits will vary depending on whether your claim is for a Pre-Service Claim, an Urgent Care Claim, a Concurrent Care Claim, a Post-Service Claim, or a Disability Claim. Read each section carefully to determine which procedure is applicable to your request for benefits:

**Pre-Service and Urgent Care Claims**

A Pre-Service Claim is a claim for a benefit for which the Plan requires approval of the benefit (in whole or in part) before medical care is obtained. Under this Plan, prior approval of services is required for all hospital admissions, complementary medicine, home health care, hospice care, certain prescription drugs, inpatient and partial day mental/nervous disorders and alcohol/substance abuse disorders.

**Important: Failure To Comply Could Result In A Minimum Penalty Of \$500 To Complete Denial Of The Claim.**

The Fund has a contract with Hines & Associates to administer Pre-Service, Urgent and Concurrent Care Claims.

For properly filed Pre-Service Claims, you and/or your doctor will be notified of a decision within 15 days from receipt of the claim unless additional time is needed. The time for response may be extended up to an additional 15 days if necessary due to matters beyond the control of Hines & Associates. You will be notified of the circumstances requiring the extension of time and the date by which a decision is expected to be rendered.

If an extension is needed because Hines & Associates needs additional information from you, the extension notice will specify the information needed. In that case you and/or your doctor will have 45 days from receipt of the notification to supply the additional information. If the information is not provided within that time, your claim will be denied. During the period in which you are allowed to supply additional information, the normal period for making a decision on the claim will be suspended. The deadline is suspended from the date of the extension notice until either 45 days or the date you respond to the request (whichever is earlier). Hines & Associates then has 15 days to make a decision on the Pre-Service Claim and notify you of the determination.

If you or your doctor improperly file a Pre-Service Claim, Hines & Associates will notify you as soon as possible but not later than 5 days after receipt of the claim, of the proper procedures to be followed in filing a claim. You will only receive notice of an improperly filed Pre-Service Claim if the claim includes (i) your name, (ii) your specific medical condition or symptom, and (iii) a specific treatment, service or product for which approval is requested. Unless the claim is re-filed properly, it will not constitute a claim.

An Urgent Care Claim is any claim for medical care or treatment with respect to which the application of the time periods for making Pre-Service claim determinations:

1. could seriously jeopardize the life or health of the claimant or the ability of the claimant to regain maximum function, or
2. in the opinion of a physician with knowledge of the claimant's medical condition, would subject the claimant to severe pain that cannot be adequately managed without the care or treatment that is the subject of the claim.

Any claim that a physician with knowledge of your medical condition determines is an Urgent Care Claim within the meaning described above, will be treated as an Urgent Care Claim. Absent a determination by that physician, whether your claim is an Urgent Care Claim will be determined by Hines & Associates applying the judgment of a prudent layperson who possesses an average knowledge of health and medicine.

If you are requesting precertification of an Urgent Care Claim, the time deadlines are different than those that apply to Pre-Service Claims. Hines & Associates will respond to you and/or your doctor with a determination by telephone as soon as possible taking into account the medical condition, but not later than 72 hours after receipt of the claim by Hines & Associates. The determination will also be confirmed in writing.



If an Urgent Care Claim is received without sufficient information to determine whether or to what extent benefits are covered or payable, Hines & Associates will notify you and/or your doctor as soon as possible, but not later than 24 hours after receipt of the claim, of the specific information necessary to complete the claim. You and/or your doctor must provide the specified information within 48 hours of receiving notice. If the information is not provided within that time, your claim will be denied. Unless the claim is re-filed properly, it will not constitute a claim.

Notice of the decision will be provided no later than 48 hours after Hines & Associates receives the specified information or the end of the period given for you to provide this information, whichever is earlier.

#### **Concurrent Claims**

A concurrent claim is a claim for additional treatment or hospital days or a claim that is reconsidered after an initial approval was made and results in a reduction, termination or extension of a benefit. (An example of this type of claim would be an inpatient hospital stay originally approved for five days that is reviewed at three days to determine if the full five days is appropriate.) In this situation a decision to reduce, terminate or extend treatment is made at the same time or "concurrently" with the provision of treatment.

A reconsideration of a benefit with respect to a concurrent claim that involves the *termination or reduction* of a previously approved benefit (other than by plan amendment or termination) will be made by Hines & Associates as soon as possible, but in any event early enough to allow you to have an appeal decided before the benefit is reduced or terminated.

Any request by a claimant to extend approved urgent care treatment will be acted upon by Hines & Associates within 24 hours of receipt of the claim, provided the claim is received at least 24 hours prior to the expiration of the approved treatment. A request to extend approved treatment that does not involve urgent care will be decided according to pre-service or post-service timeframes, whichever applies.

#### **Post-Service Claim**

The following procedure applies to Post-Service Claims. A Post-Service Claim is a claim that is not a Pre-Service, Urgent Care, or Concurrent Claim (for example, a claim submitted for payment after health services and treatment have been obtained).

Your provider should submit all claims on your behalf to the Fund Office or to CCN. If you experience a problem submitting a claim, call the Fund Office.

You do not have to submit an additional claim form with your bills or statements, if you have filed the annual health claim during the calendar year. Mail any further bills or statements for any medical or hospital services covered by the Plan to the address shown on your I.D. Card as soon as you receive them. Your provider may also submit bills on your behalf.

Ordinarily, you will be notified of the decision on your Post-Service Claim within 30 days from the Plan's receipt of the claim. This period may be extended once by the Plan for up to 15 days if the extension is necessary due to matters beyond the control of the



Plan. If an extension is necessary, you will be notified before the end of the initial 30-day period of the circumstances requiring the extension of time and the date by which the Plan expects to render a decision.

If an extension is needed because the Plan needs additional information from you, the extension notice will specify the information needed. In that case you will have 45 days from receipt of the notification to supply the additional information. If the information is not provided within that time, your claim is deemed denied. During the period in which you are allowed to supply additional information, the normal period for making a decision on the claim will be suspended. The deadline is suspended from the date of the extension notice until either 45 days or until the date you respond to the request (whichever is earlier). The Plan then has 15 days to make a decision on a Post-Service Claim and notify you of the determination.

#### **DISABILITY CLAIMS (WEEKLY ACCIDENT AND SICKNESS BENEFIT)**

You must file a claim for Weekly Accident and Sickness Benefits with the Fund Office no later than 90 days after the date your disability began.

For Disability Claims, the Plan will make a decision on the claim and notify you of the decision within 45 days. If the Plan requires an extension of time due to matters beyond the control of the Plan, the Plan will notify you of the reason for the delay and when the decision will be made. This notification will occur before the expiration of the 45-day period. A decision will be made within 30 days of the time the Plan notifies you of the delay. The period for making a decision may be delayed an additional 30 days, provided the Plan administrator notifies you, prior to the expiration of the first 30-day extension period, of the circumstances requiring the extension and the date as of which the Plan expects to render a decision.

If an extension is needed because the Plan needs additional information from you, the extension notice will specify the information needed. In that case you will have 45 days from receipt of the notification to supply the additional information. If the information is not provided within that time, your claim will be denied. During the period in which you are allowed to supply additional information, the normal period for making a decision on the claim will be suspended. The deadline is suspended from the date of the extension notice until either 45 days or until the date you respond to the request (whichever is earlier). Once you respond to the Plan's request for the information, you will be notified of the Plan's decision on the claim, or the need for an extension, within 30 days.

#### **Notice Of A Denied Claim**

You will be provided with written notice of a denial of a claim (whether denied in whole or in part). This notice will state:

- The specific reason(s) for the determination.
- Reference to the specific Plan provision(s) on which the determination is based.
- A description of any additional material or information necessary to perfect the claim, and an explanation of why the material or information is necessary.

- A description of the appeal procedures (including voluntary appeals, if any) and applicable time limits.
- A statement of your right to bring a civil action under ERISA Section 502(a) following an adverse benefit determination on review.
- If an internal rule, guideline or protocol was relied upon in deciding your claim, you will receive either a copy of the rule or a statement that it is available upon request at no charge.
- If the determination was based on the absence of medical necessity, or because the treatment was experimental or investigational, or other similar exclusion, you will receive an explanation of the scientific or clinical judgment for the determination applying the terms of the Plan to your claim, or a statement that it is available upon request at no charge.

#### **Appeal Process for Denied Claims**

If your claim is denied in whole or in part, or if you disagree with the decision made on a claim, you may ask for a review. Your request for review must be made in writing to the Fund Office and must be received within 180 days after you receive a notice of denial. Appeals involving Urgent Care Claims may be made orally by calling the Fund Administrator at (800) 344-1515 for urgent and concurrent claim appeals only. There is a second level of appeal for Post-Service and Disability claims, and appeals to the second level concerning those claims must be received by the Fund Office within 60 days of the date of the decision at the first level of appeal.

#### **APPEAL PROCESS**

The appeal process works as follows:

##### **Urgent, Pre-Service and Concurrent Claim Appeals**

For Urgent, Pre-Service and Concurrent Claim Appeals, there is one level of appeal. Appeals should be made in writing to the Fund Office. A subcommittee of the Board of Trustees will review Urgent, Pre-Service and Concurrent Claim appeals. In certain circumstances such as Urgent Claim appeals where medical conditions exist that require an expedited review process, appeals may be made orally via telephone.

##### **Post-Service and Disability Claim Appeals**

For Post-Service and Disability claims appeals, there is a two-level appeal process. Appeals at both levels must be in writing and must be submitted to the Fund Office. The first level of appeal will consist of a review by the Fund Administrator. First level appeals must be received by the Fund Office within 180 days after you receive the Fund's notice of its denial of your claim. If the Fund Administrator denies your first level appeal, you have the right to a second level appeal to the full Board of Trustees. Second level appeals must be received by the Fund Office within 60 days of the date of the Fund Administrator's decision at the first level.

##### **Information To Which You Are Entitled**

You have the right to review documents relevant to your claim. A document, record or other information is relevant if it was relied upon by the Plan in making the decision; it was submitted, considered or generated (regardless of whether it was relied upon in making the decision); it demonstrates compliance with the Plan's administrative processes for ensuring consistent decision making; or it constitutes a statement of Plan policy regarding the denied treatment or service.

Upon request, you will be provided with the identification of medical or vocational experts, if any, who gave advice to the Plan on your claim, without regard to whether their advice was relied upon in deciding your claim.

A different person will review your claim than the one who originally denied the claim or the previous appeal. The reviewer will not give deference to the previous adverse benefit determinations. The decision will be made on the basis of the record, including such additional documents and comments that may be submitted by you.

If your claim was denied on the basis of a medical judgment (such as a determination that the treatment or service was not medically necessary, or was investigational or experimental), a health care professional who has appropriate training and experience in a relevant field of medicine will be consulted.

**Timing of Notice of Decision on Appeal**

- **Pre-Service Claims:** You will be sent a notice of decision on review within 30 days of receipt of the appeal by the Fund Office.
- **Urgent Care Claims:** You will be notified of a decision on your appeal, either orally or in writing (or both) within 72 hours of receipt of the appeal by the Fund Office.
- **Post-Service Claims:** For first level appeals, a decision will be made on the appeal within 30 days of receipt of the appeal by the Fund Administrator. For second level appeals, decisions will be made at the next regularly scheduled meeting of the Board of Trustees following receipt of your request for review. However, if your request for review is received within 30 days of the next regularly scheduled meeting, your request for review will be considered at the second regularly scheduled meeting following receipt of your request. In special circumstances, a delay until the third regularly scheduled meeting following receipt of your request for review may be necessary. You will be advised in writing in advance if this extension will be necessary. Once a decision on review of your claim has been reached, the Fund Office will give you written notice of the decision as soon as possible, but no later than 5 days after the decision has been reached.
- **Disability Claims:** For first level disability claim appeals a decision will be made by the Fund Administrator within 45 days of receipt of the appeal at the Fund Office. If the Fund Administrator determines that special circumstances require an extension of time, then you will receive a written notice of the extension before the end of the 45-day period. The notice will include the reasons required for the extension and the approximate date the Plan expects to make a decision.

For second level appeals, decisions will be made at the next regularly scheduled meeting of the Board of Trustees following receipt of your request for review. However, if your request for review is received within 30 days of the next regularly scheduled meeting, your request for review will be considered at the second regularly scheduled meeting following receipt of your request. In special circumstances, a delay until the third regularly scheduled meeting following receipt of your request for review may be necessary. You will be advised in writing in advance if this extension

will be necessary. Once a decision on review of your claim has been reached, the Fund Office will give you written notice of the decision as soon as possible, but no later than 5 days after the decision has been reached.

- **Concurrent Claims:** Appeals of concurrent claims involving a termination or reduction of benefits of previously approved care shall be completed before the termination or reduction. The claimant shall be given notice sufficiently in advance of the termination or reduction to allow the claimant to appeal before the benefit is terminated or reduced. Appeals of concurrent claims involving an extension of care shall be conducted within the timeframe for urgent, pre-service or post-service appeals described above, depending on which category applies to the appeal.

#### **Notice of Decision on Review**

The decision on any review of your claim will be given to you in writing. The notice of a denial of a claim on review will state:

- The specific reason(s) for the determination.
- Reference to the specific Plan provision(s) on which the determination is based.
- A statement that you are entitled to receive reasonable access to and copies of all documents relevant to your claim, upon request and free of charge.
- A statement of your right to bring a civil action under ERISA Section 502(a) following an adverse benefit determination on review.
- If an internal rule, guideline or protocol was relied upon by the Plan, you will receive either a copy of the rule or a statement that it is available upon request at no charge.
- If the determination was based on medical necessity, or because the treatment was experimental or investigational, or other similar exclusion, you will receive an explanation of the scientific or clinical judgment for the determination applying the terms of the Plan to your claim, or a statement that it is available upon request at no charge.

#### **Limitation on When a Lawsuit May Be Started**

You may not start a lawsuit to obtain benefits until after you have exhausted all levels of appeal and final decisions have been reached on those appeals, or until the appropriate time frame described above has elapsed since you filed a request for review and you have received a final decision or notice that an extension will be necessary to reach a final decision. The law also permits you to pursue your remedies under section 502(a) of the Employee Retirement Income Security Act without exhausting these appeal procedures if the Plan has failed to follow them. No lawsuit to recover Plan benefits may be started more than 15 months after the date of loss (that is, the date you incurred the expense you are seeking to have the Plan pay) upon which the lawsuit is based. Because the Plan grants its fiduciaries discretionary authority to determine eligibility for benefits and to construe the terms of the Plan, the issue in a lawsuit will be limited to whether or not the Board of Trustees (or its delegates, including the subcommittee for Urgent Care, Pre-service and Concurrent Claims) acted arbitrarily or capriciously in making its determination. No lawsuit to recover Plan benefits may be started more than 12 months after the date the Board of Trustees makes its final decision on an appeal, or after the date the Fund was required but failed to act in accordance with its appeal procedures.

## YOUR ERISA RIGHTS

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As a participant in the New England Carpenters Health Benefits Fund, you are entitled to certain rights and protections under the Employee Retirement Income Security Act of 1974 (ERISA). ERISA provides that all Plan participants are entitled to:

### Receive Information About Your Plan and Benefits

- Examine, without charge, at the Fund Administrator's office and at other specified locations, such as worksites and union halls, all documents governing the Plan, including insurance contracts and Collective Bargaining Agreements, and a copy of the latest annual report (Form 5500 Series) filed by the Fund with the U.S. Department of Labor and available at the Public Disclosure Room of the Employee Benefits Security Administration.
- Obtain, upon written request to the Fund Administrator, copies of documents governing the operation of the Plan, including insurance contracts and Collective Bargaining Agreements, and copies of the latest annual report (Form 5500 Series) and updated Summary Plan Description. The Administrator may make a reasonable charge for the copies.
- Receive a summary of the Fund's annual financial report. The Fund Administrator is required by law to furnish each participant with a copy of this summary annual report.
- Continue health care coverage for yourself, spouse or dependents if there is a loss of coverage under the Plan as a result of a qualifying event. You or your dependents may have to pay for such coverage. Review this Summary Plan Description and the documents governing the Plan on the rules governing your COBRA Continuation Coverage rights.
- Reduce or eliminate exclusionary periods of coverage for pre-existing conditions under your group health plan, if you have creditable coverage from another plan. When you lose coverage under the New England Carpenters Health Benefits Fund, your group health plan or health insurance issuer should provide you with a certificate of creditable coverage, free of charge when:
  - You become entitled to elect COBRA Continuation Coverage,
  - Your COBRA coverage ceases, if you request it before losing coverage, or if you request it up to 24 months after losing coverage.

### Prudent Actions By Plan Fiduciaries

In addition to creating rights for Fund participants, ERISA imposes duties upon the people who are responsible for the operation of the employee benefit plan. The people who operate your Fund, called "fiduciaries" of the Fund, have a duty to do so prudently and in the interest of you and other Fund participants and beneficiaries. No one, including your employer, your union, or any other person, may fire you or otherwise discriminate against you in any way to prevent you from obtaining a welfare benefit or exercising your rights under ERISA.

### Enforce Your Rights

If your claim is denied or ignored, in whole or in part, you have a right to know why this was done, to obtain copies of documents relating to the decision without charge, and to appeal any denial, all within certain time schedules.

Under ERISA, there are steps you can take to enforce the above rights. For instance, if you request a copy of the Plan documents or the latest annual report from the Fund and do not receive them within 30 days, you may file suit in a federal court. In such a case, the court may require the Fund Administrator to provide the materials and pay you up to \$110 a day until you receive the materials, unless the materials were not sent because of reasons beyond the control of the Administrator.

If you have a claim for benefits that is denied or ignored, in whole or in part, you may file suit in a state or federal court. In addition, if you disagree with the Fund's decision or lack thereof concerning the qualified status of a domestic relations order or a medical child support order, you may file suit in federal court. If it should happen that Fund fiduciaries misuse the Fund's money, or if you are discriminated against for asserting your rights, you may seek assistance from the U.S. Department of Labor, or you may file suit in a federal court. The court will decide who should pay court costs and legal fees. If you are successful the court may order the person you have sued to pay these costs and fees. If you lose, the court may order you to pay these costs and fees, for example if it finds your claim is frivolous.

#### **Assistance with Your Questions**

If you have any questions about your Plan, you should contact the Fund Administrator. If you have any questions about this statement or about your rights under ERISA, or if you need assistance in obtaining documents from the Fund Administrator, you should contact the nearest office of the Employee Benefits Security Administration, U.S. Department of Labor, listed in your telephone directory or the Division of Technical Assistance and Inquiries, Pension and Welfare Benefits Administration, U.S. Department of Labor, 200 Constitution Avenue, N.W., Washington D.C. 20210. You may also obtain certain publications about your rights and responsibilities under ERISA by calling the publications hotline at the Employee Benefits Security Administration.

## PLAN FACTS

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<b>Name of Plan</b>	The New England Carpenters Health Benefits Fund
<b>Type of Plan</b>	A self-funded Employee Health and Welfare Benefit Plan that provides coverage for medical care, prescription drugs, dental care, vision care, weekly accident and sickness benefits, life insurance and accidental death and dismemberment benefits to eligible members and their qualified dependents.
<b>Name of Plan Sponsor</b>	Board of Trustees New England Carpenters Health Benefits Fund
<b>Fund Office Address</b>	350 Fordham Road, Wilmington, MA 01887
<b>Agent for Service of Legal Process</b>	Service of legal process may be made upon any Fund Trustee.
<b>Plan Administrator</b>	Board of Trustees New England Carpenters Health Benefits Fund
<b>Type of Administration of the Plan</b>	Collectively Bargained, jointly trustee labor management trust
<b>Plan Number</b>	501
<b>IRS Employer Identification Number</b>	04-2191579
<b>Plan Fiscal Year</b>	January 1—December 31
<b>Sources of Financing</b>	<p>Payments made to the trust by individual employers under the provisions of the Collective Bargaining or Participation Agreements, employee contributions, and any income earned from investment of employer and employee contributions.</p> <p>The Fund Office will provide you, upon written request, with information as to whether a particular employer is contributing to this Plan on behalf of Participants working under the Collective Bargaining Agreement and, if so, with that employer's address.</p> <p>All monies are used exclusively for providing benefits to eligible employees, early retirees, and their dependents, and the paying of all expenses incurred with respect to the operation of the Plan. The Trustees shall review annually the funding status of the Plan.</p>
<b>Organizations Through Which Plan Benefits are Provided or Administered</b>	
<b>PPO Network Access Only</b>	Medical Care CCN
<b>PPO Network Access Only</b>	Substance Abuse and Mental Health CCN
<b>Utilization Review Vendor</b>	Hines & Associates
<b>Self-funded</b>	Prescription Drugs Ullicare Rx/Medco
<b>Self-funded, Network access and dental claims administration</b>	Dental Care Delta Dental
<b>Self-funded benefit, Network access and vision claims administration</b>	Vision Care Davis Vision
<b>Insurance Policies</b>	Life Insurance and Accidental Death and Dismemberment Insurance— Hartford Life Insurance Company



#### **The Board of Trustees**

The Board of Trustees is made up of an equal number of Representatives and Union Representatives who serve without compensation. Under a Trust Agreement, the Board has full authority and discretion to operate and administer this Plan.

#### **Discretionary Authority of the Board of Trustees and its Designees**

In carrying out their respective responsibilities under the Plan, the Board of Trustees, the Fund Administrator and other individuals with delegated responsibility for the administration of the Plan will have discretionary authority to interpret the terms of the Plan and to determine eligibility and entitlement to Plan benefits in accordance with the terms of the Plan. Any interpretation or determination will be given full force and effect, unless it can be shown that the interpretation or determination was arbitrary and capricious.

#### **Collective Bargaining Agreement**

A collective bargaining agreement is a written agreement between a union and an employer that requires the employer to make contributions to the Fund on behalf of its employees. To inquire about whether a particular employer contributes to this Fund, or to request a copy of the collective bargaining agreement, contact the Fund Office.

#### **Plan Amendment and Termination**

The Board of Trustees reserves the right to terminate or amend the Plan including the right to amend or terminate benefits or eligibility for any class of participant, including retirees, when in their sole discretion they determine such action is in the best interest of the Fund and its participants. Eligibility requirements are reviewed regularly by the Trustees.

In addition, the Plan may be terminated by the Trustees if there is no longer an agreement in effect between the Employers and the Union requiring contributions to the Health Benefits Fund.

Should the Plan terminate, the Trustees will apply remaining assets of the Fund to continue benefits beyond the date of termination. The Trustees reserve the right to amend the eligibility rules at the time of termination. Retiree benefits are funded from current contributions and are not guaranteed or vested. In any case, the Trustees will use any remaining assets of the Fund to provide benefits and pay administration expenses or otherwise to carry out the purpose of the Plan in accordance with the Plan Document and Trustee Agreement until the entire remainder of the Fund has been disbursed.



## SCHEDULE OF BENEFITS FOR PLAN I

The chart that follows highlights the benefits of the New England Carpenters Health Benefits Fund. For more detailed information, contact the Fund Office.

<b>Your Calendar Year Deductible</b>	\$150 per person \$300 per family
<b>Your Calendar Year Out-of-Pocket Maximum</b>	\$1,500 per person
<b>Maximum Benefit the Plan Will Pay Per Person Per Lifetime</b>	\$1,000,000

The Life Insurance benefit is available to members and spouses. Accidental Death and Dismemberment and Weekly Accident and Sickness benefits are available to Members only.

<b>Life Insurance</b>	\$20,000 for Member; \$2,000 for spouse
<b>Accidental Death and Dismemberment</b>	Refer to page 49
<b>Weekly Accident and Sickness</b>	\$250 per week for up to 26 weeks per period of disability

The following schedule shows the percentage of charges that the Fund pays under Plan I, whether medical services are obtained in the PPO network or out-of-network. Note: Charges for benefits provided by PPO network providers are based on a negotiated contract. Charges for benefits provided by out-of-network providers are based on reasonable and customary rates as described on page 27. You are responsible for any provider charges in excess of reasonable and customary rates.

	<b>Plan Pays PPO Network</b>	<b>Plan Pays Out-of-Network</b>
<b>Ambulance Service</b>	90% after deductible. Air Ambulance service payable at 90% after deductible to a maximum of \$2,000 per life-threatening emergency	85% after deductible. Air Ambulance service payable at 85% after deductible to a maximum of \$2,000 per life-threatening emergency
<b>Cardiac Rehabilitation</b>	90% after deductible when medically necessary following heart attack or stroke, upon recommendation of and with supervision of attending physician, to a lifetime maximum of \$3,000	85% after deductible when medically necessary following heart attack or stroke, upon recommendation of and with supervision of attending physician, to a lifetime maximum of \$3,000
<b>Chiropractic Care</b>	100% after \$10 copay per visit to a calendar year maximum of 20 visits per person	85% after deductible to a calendar year maximum of 20 visits per person

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**SCHEDULE OF BENEFITS FOR PLAN I** CONTINUED

	<b>Plan Pays PPO Network</b>	<b>Plan Pays Out-of-Network</b>
<b>Diagnostic Laboratory and X-Ray</b>	100%	85% after deductible
<b>Durable Medical Equipment</b> (requires physician letter of medical necessity)	90% after deductible. Payments will not exceed the actual purchase price	85% after deductible. Payments will not exceed the actual purchase price
<b>Emergency Room</b> (refer to page 31)	90% after deductible. \$50 penalty for non-life-threatening care	85% after deductible. \$50 penalty for non-life-threatening care
<b>Hearing Aids</b>	Up to \$1,500 per hearing aid to a maximum of \$3,000 once every five-year period. Covered through selected providers only. Contact the Fund Office for a listing and to set up an appointment	
<b>Home Health Care</b> (requires physician letter of medical necessity)	See page 37 for specific coverage information	See page 37 for specific coverage information
<b>Hospice Care</b>	100% after deductible	85% after deductible
<b>Hospital Room and Board</b>	100% of the first \$10,000, then payable at 90% after deductible	85% after deductible
<b>Hospital Physician Expense Benefit</b>	90% after deductible	85% after deductible
<b>Infertility Treatment</b>	Lifetime maximum \$5,000. Lab and x-ray: 100% of PPO fee; Surgeon's fee: 100% of PPO fee schedule, otherwise subject to R&C charges; Anesthesia: 100% of PPO fee. All other services subject to deductible, then payable at 90%.	Lifetime maximum \$5,000. After deductible, 85% of R&C charges to the lifetime maximum of \$5,000.
<b>Mental Health Treatment (Inpatient)</b>	90% after deductible to a calendar year maximum of 30 days per person	85% after deductible to a calendar year maximum of 30 days per person
<b>Mental Health Treatment (Outpatient)</b>	100% after \$10 copay per visit, to a maximum of 25 visits per person per calendar year	50% after deductible to a maximum of 25 visits per person per calendar year
<b>Occupational Therapy</b> (requires physician letter of medical necessity)	100% after \$10 copay per visit up to combined lifetime maximum of \$40,000 for physical, speech and occupational therapy	100% up to combined lifetime maximum of \$40,000 for physical, speech and occupational therapy
<b>Office Visits (Illness)</b>	100% after \$10 copay per visit	85% after deductible

**SCHEDULE OF BENEFITS FOR PLAN I** CONTINUED

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	<b>Plan Pays PPO Network</b>	<b>Plan Pays Out-of-Network</b>
<b>Organ Transplants</b>	\$250,000 per transplant maximum. Hospital: 100% of the first \$10,000 then 90% after deductible Surgeon's fee: 100% of PPO fee schedule otherwise subject to R&C charges. Anesthesia: 100% of PPO fee schedule	\$250,000 per transplant maximum. Hospital: 85% after deductible Surgeon's fee: 85% of R&C charges after deductible Anesthesia: 85% of charges after deductible
<b>Physical Exams (includes all lab, x-ray and immunizations)</b>	Covered for Member and spouse only Paid at 100% up to calendar year maximum of \$150	
<b>Physical Therapy (requires physician letter of medical necessity)</b>	100% after \$10 copay per visit, up to a combined lifetime maximum of \$40,000 for physical, speech and occupational therapy	85% after deductible, up to a combined lifetime maximum of \$40,000 for physical, speech and occupational therapy
<b>Podiatrist Services</b>	100% after \$10 copay to a calendar year maximum of \$500 per person	85% after deductible to a calendar year maximum of \$500 per person
<b>Prescription Drugs (Mail Order, 90-day supply)</b>	\$20 copay for generics, \$40 for Brand Preferred and \$60 for Brand Non-Preferred	
<b>Prescription Drugs (Retail, 34-day supply)</b>	\$10 copay for generics, \$20 for Brand Preferred and \$30 for Brand Non-Preferred	
<b>Skilled Nursing Facility</b>	100% of the first \$10,000 then payable at 90% after deductible	85% after deductible
<b>Speech Therapy (requires physician letter of medical necessity)</b>	90% after deductible up to a combined lifetime maximum of \$40,000 for physical, speech and occupational therapy	85% after deductible up to a combined lifetime maximum of \$40,000 for physical, speech and occupational therapy
<b>Substance Abuse Treatment (Inpatient)</b>	90% after deductible to a maximum of 30 days per person per calendar year. Maximum of two lifetime occurrences per person	85% after deductible to a maximum of 30 inpatient days per calendar year per person. Maximum of two lifetime occurrences per person
<b>Substance Abuse Treatment (Outpatient)</b>	100%, after a \$10 copay, to a maximum of \$500 per person per calendar year	85% after deductible to a maximum of \$500 per person per calendar year
<b>Surgeon's Expenses</b>	100% of PPO fee schedule otherwise subject to R&C schedule	85% of R&C charges after deductible
<b>Temporomandibular Joint Disorders (TMJ)</b>	100% after a \$10 copay to a lifetime maximum of \$1,500, within limitations covered under Plan exclusions (page 52)	85% after deductible to a lifetime maximum of \$1,500, within limitations covered under Plan exclusions (page 52)
<b>Well-Child Care (includes all lab, x-ray and immunizations)</b>	100% after a \$10 copayment for children from birth through age 5; For children 6 and older, 100% to a calendar year maximum of \$70 until they turn 19 (or through 23 if a full-time student)	

## SCHEDULE OF DENTAL BENEFITS FOR PLAN I

The following chart shows the benefits payable when you use a participating Delta Dental provider. For out-of-network benefits, you will be billed for any amount that your out-of-network dentist charges that is more than the pre-negotiated Delta Dental network charge. Please refer to your Delta Dental benefits guide for more specific coverage information.

### Dental Care Benefits

Type I Plan Pays 100%	Type II Plan Pays 80%	Type III Plan Pays 50%	Orthodontics Plan Pays 100%
<b>Diagnostic</b> One complete initial oral exam and charting Periodic oral exams Full mouth x-rays Bitewing x-rays Single tooth x-rays Sturdy models and casts  <b>Preventive</b> Cleaning Fluoride treatments Space maintainers Sealants	<b>Restorative</b> Amalgam fillings Composite fillings Treatment fillings Stainless steel crowns  <b>Oral Surgery</b> Simple extractions Surgical extractions  <b>Periodontics</b> Periodontal surgery (including gingivectomy) Scaling and root planing Gingival curettage  <b>Endodontics</b> Root canal therapy Pulpal therapy Pulp Capping  <b>Prosthetic Maintenance</b> Bridge or Denture Repair Rebase or Reline of Dentures Recement Crowns, Inlays and Onlays  <b>Emergency Dental Care</b>	<b>Prosthodontic</b> Complete or partial dentures, fixed bridges and crowns when part of a bridge; once every 60 months per tooth  <b>Major Restorative</b> Crowns, inlays and onlays when teeth cannot be restored with regular fillings due to severe decay or fracture; once every 60 months per tooth	<b>Orthodontics</b> Complete Orthodontic Examination Active Orthodontic Treatment (Comprehensive or limited including appliances)

## SCHEDULE OF BENEFITS FOR PLAN II

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The chart that follows highlights the benefits of the New England Carpenters Health Benefits Fund. For more detailed information, contact the Fund Office.

<b>Your Calendar Year Deductible</b>	\$300 per person \$600 per family
<b>Your Calendar Year Out-of-Pocket Maximum</b>	\$3,000 per person
<b>Maximum Benefit the Plan Will Pay Per Person Per Lifetime</b>	\$500,000

The Life Insurance benefits are available to Members and spouses. Accidental Death and Dismemberment Insurance benefits are available to Members only.

<b>Life Insurance</b>	\$10,000 for Member; \$2,000 for spouse
<b>Accidental Death and Dismemberment</b>	Refer to page 49

The following schedule shows the percentage of charges that the Fund pays under Plan II, whether medical services are obtained in the PPO network or out-of-network. Note: Charges for benefits provided by PPO network providers are based on a negotiated contract. Charges for benefits provided by out-of-network providers are based on reasonable and customary rates as described on page 27. You are responsible for any provider charges in excess of reasonable and customary rates.

	<b>Plan Pays PPO Network</b>	<b>Plan Pays Out-of-Network</b>
<b>Ambulance Service</b>	80% after deductible. Air Ambulance service payable at 80% after deductible to a maximum of \$2,000 per life-threatening emergency	75% after deductible. Air Ambulance service payable at 75% after deductible to a maximum of \$2,000 per life-threatening emergency
<b>Cardiac Rehabilitation</b>	80% after deductible when medically necessary following heart attack or stroke, upon recommendation of and with supervision of attending physician to a lifetime maximum of \$1,500	75% after deductible when medically necessary following heart attack or stroke, upon recommendation of and with supervision of attending physician, to a lifetime maximum of \$1,500
<b>Chiropractic Care</b>	100% after \$10 copay per visit to a calendar year maximum of 20 visits per person	75% after deductible to a calendar year maximum of 20 visits per person
<b>Diagnostic Laboratory and X-Ray</b>	100%	75% after deductible

**SCHEDULE OF BENEFITS FOR PLAN II**

CONTINUED

	<b>Plan Pays PPO Network</b>	<b>Plan Pays Out-of-Network</b>
<b>Durable Medical Equipment</b> (requires physician letter of medical necessity)	80% after deductible. Payments will not exceed the actual purchase price	75% after deductible. Payments will not exceed actual purchase price
<b>Emergency Room</b> (refer to page 31)	80% after deductible \$50 penalty for non-life-threatening care	75% after deductible \$50 penalty for non-life-threatening care
<b>Hearing Aids</b>	Up to \$1,500 per hearing aid to a maximum of \$3,000 once every five-year period. Covered through selected providers only. Contact the Fund Office for a listing and to set up an appointment.	
<b>Home Health Care</b> (requires physician letter of medical necessity)	See page 37 for specific coverage information	See page 37 for specific coverage information
<b>Hospice Care</b>	100% after deductible	75% after deductible
<b>Hospital Room and Board</b>	80% after deductible	75% after deductible
<b>Hospital Physician Expense</b>	80% after deductible	75% after deductible
<b>Infertility Treatment</b>	Lifetime maximum \$5,000. Lab and x-ray: 100% of PPO fee; Surgeon's fee: 100% of PPO fee schedule, otherwise subject to R&C charges Anesthesia: 100% of PPO fee. All other services subject to deductible, then payable at 80%.	Lifetime maximum \$5,000. After deductible, 75% of R&C charges to the lifetime maximum of \$5,000.
<b>Mental Health Treatment (Inpatient)</b>	80% after deductible to a calendar year maximum of 30 days per person	75% after deductible to a calendar year maximum of 30 days per person
<b>Mental Health Treatment (Outpatient)</b>	100% after \$10 copay per visit, to a maximum of 10 visits per person per calendar year	50% after deductible to a maximum of 10 visits per person per calendar year
<b>Occupational Therapy</b> (requires physician letter of medical necessity)	100% after \$10 copay per visit up to a combined lifetime maximum of \$30,000 for physical, speech and occupational therapy	100% up to a combined lifetime maximum of \$30,000 for physical, speech and occupational therapy
<b>Office Visits (Illness)</b>	100% after \$10 copay per visit	75% after deductible
<b>Organ Transplants</b>	\$250,000 per transplant maximum Hospital: 80% after deductible Surgeon's fee: 100% of PPO fee schedule otherwise subject to R&C charges Anesthesia: 100% of PPO fee schedule	\$250,000 per transplant maximum Hospital: 75% after deductible Surgeon's fee: 75% of R&C charges after deductible Anesthesia: 75% of charges after deductible

**SCHEDULE OF BENEFITS FOR PLAN II** CONTINUED

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	<b>Plan Pays PPO Network</b>	<b>Plan Pays Out-of-Network</b>
<b>Physical Exams</b> (includes all lab, x-ray and immunizations)	Covered for Member and spouse only Paid at 100% to a calendar year maximum of \$75	
<b>Physical Therapy</b> (requires physician letter of medical necessity)	100% after \$10 copay per visit, up to a combined lifetime maximum of \$30,000 for physical, speech and occupational therapy	75% after deductible, up to a combined lifetime maximum of \$30,000 for physical, speech and occupational therapy
<b>Podiatrist Services</b>	100% after \$10 copay to a calendar year maximum of \$500 per person	75% after deductible to a calendar year maximum of \$500 per person
<b>Prescription Drugs</b> (Mail Order, 90-day supply)	\$20 copay for generics, \$40 for Brand Preferred and \$60 for Brand Non-Preferred	
<b>Prescription Drugs</b> (Retail, 34-day supply)	\$10 copay for generics, \$20 for Brand Preferred and \$30 for Brand Non-Preferred	
<b>Skilled Nursing Facility</b>	80% after deductible	75% after deductible
<b>Speech Therapy</b> (requires physician letter of medical necessity)	80% after deductible up to a combined lifetime maximum of \$30,000 for physical, speech and occupational therapy	75% after deductible up to a combined lifetime maximum of \$30,000 for physical, speech and occupational therapy
<b>Substance Abuse Treatment (Inpatient)</b>	80% after deductible to a maximum of 30 days per person per calendar year. Maximum of two lifetime occurrences per person	75% after deductible to a maximum of 30 days per person per calendar year. Maximum of two lifetime occurrences per person
<b>Substance Abuse Treatment (Outpatient)</b>	100% after \$10 copay to a maximum of \$500 per person per calendar year	75% after deductible to a maximum of \$500 per person per calendar year
<b>Surgeon's Expenses</b>	100% of PPO fee schedule otherwise subject to R&C charges	75% of R&C charges after deductible
<b>Temporomandibular Joint Disorders (TMJ)</b>	100% after \$10 copay to a lifetime maximum of \$1,000 within limitations covered under Plan Exclusions (page 52)	75% after deductible to a lifetime maximum of \$1,000 within limitations covered under Plan Exclusions (page 52)
<b>Well-Child Care</b> (includes all lab, x-ray and immunizations)	100% after \$10 copayment for children from birth through age 5; not covered for children age 6 and older	Not covered

## SCHEDULE OF BENEFITS FOR THE RETIREE PLAN

The chart that follows highlights the benefits of the New England Carpenters Health Benefits Fund. For more detailed information, contact the Fund Office.

<b>Your Calendar Year Deductible</b>	\$250 per individual
<b>Your Calendar Year Out-of-Pocket Maximum</b>	\$3,000 per individual
<b>Maximum Benefit the Plan Will Pay Per Person Per Lifetime</b>	\$1,000,000

**!! YOU MUST USE THE PPO NETWORK TO RECEIVE BENEFITS FROM THE RETIREE PLAN UNLESS YOU LIVE OUTSIDE A 20-MILE RADIUS FROM A PREFERRED PROVIDER.**

The following schedule shows the percentage of charges that the Fund pays under the Retiree Plan whether medical services are obtained in the PPO Network or Out-of-Area. Note: Charges for benefits provided by PPO network providers are based on a negotiated contract. Charges for benefits provided by out-of-area providers are based on reasonable and customary rates described on page 27. You are responsible for any provider charges in excess of the reasonable and customary rates.

	<b>Plan Pays PPO Network</b>	<b>Out-of-Area Benefits</b>
<b>Ambulance Service</b>	80% after deductible. Air Ambulance service payable at 80% after deductible to a maximum of \$2,000 per life-threatening emergency	
<b>Cardiac Rehabilitation</b>	80% after deductible, when medically necessary following heart attack or stroke, upon recommendation of and with supervision of attending physician to a lifetime maximum of \$1,500	80% after deductible when medically necessary following heart attack or stroke, upon recommendation of and with supervision of attending physician, to a lifetime maximum of \$1,500
<b>Chiropractic Care</b>	100% after \$10 copay per visit to a calendar year maximum of 20 visits per person	80% after deductible to a calendar year maximum of 20 visits per person
<b>Diagnostic Laboratory and X-Ray</b>	100%	80% after deductible
<b>Durable Medical Equipment (requires physician letter of medical necessity)</b>	80% after deductible. Payments will not exceed the actual purchase price	
<b>Emergency Room</b>	80% after deductible. 50% after deductible for non-life-threatening care	
<b>Hearing Aids</b>	Up to \$1,500 per hearing aid to a maximum of \$3,000 once every five-year period. Covered through selected providers only. Call the Fund Office for a listing and to set up an appointment.	
<b>Home Health Care (requires physician letter of medical necessity)</b>	See page 37 for specific information	See page 37 for specific information
<b>Hospice Care/Extended Care Facility</b>	Not covered	
<b>Hospital Physician Expenses</b>	80% after deductible	
<b>Hospital Room and Board</b>	80% after deductible	
<b>Infertility Treatment</b>	Not covered	



**SCHEDULE OF BENEFITS FOR THE RETIREE PLAN**

CONTINUED

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	<b>Plan Pays PPO Network</b>	<b>Out-of-Area Benefits</b>
<b>Mental Health Treatment (Inpatient)</b>	80% after deductible to a maximum of 15 days per calendar year per person	
<b>Mental Health Treatment (Outpatient)</b>	100% after \$10 copay to a calendar year maximum of 25 visits per person	50% after deductible to a calendar year maximum of 25 visits per person
<b>Occupational Therapy (requires physician letter of medical necessity)</b>	100% after \$10 copay up to a combined lifetime maximum of \$30,000 for physical, speech and occupational therapy	100% up to a combined lifetime maximum of \$30,000 for physical, speech and occupational therapy
<b>Office Visits (Illness)</b>	100% after \$10 copay	80% after deductible
<b>Organ Transplants</b>	\$250,000 per transplant maximum Hospital: 80% after deductible Surgeon's fee: 100% of PPO fee schedule otherwise subject to R&C charges Anesthesia: 100% of PPO fee schedule	\$250,000 per transplant maximum Hospital: 70% after deductible Surgeon's fee: 70% of R&C charges after deductible Anesthesia: 70% of charges after deductible
<b>Physical Exams (includes all lab, x-ray and immunizations)</b>	Covered for Members and spouses only Paid at 100% to a calendar year maximum of \$100	
<b>Physical Therapy (requires physician letter of medical necessity)</b>	100% after \$10 copay up to combined lifetime maximum of \$30,000 for physical, speech and occupational therapy	80% after deductible up to combined lifetime maximum of \$30,000 for physical, speech and occupational therapy
<b>Podiatrist Services</b>	100% after \$10 copay up to a calendar year maximum of \$500 per person	80% after deductible up to a calendar year maximum of \$500 per person
<b>Prescription Drugs (Mail Order, 90-day supply)</b>	\$20 copay for generics, \$40 for Brand Preferred and \$60 for Brand Non-Preferred. Calendar year maximum of \$15,000 per person	
<b>Prescription Drugs (Retail, 34-day supply)</b>	\$10 copay for generics, \$20 for Brand Preferred and \$30 for Brand Non-Preferred. Calendar year maximum of \$15,000 per person	
<b>Speech Therapy (requires physician letter of medical necessity)</b>	80% after deductible up to a combined lifetime maximum of \$30,000 for physical, speech and occupational therapy	80% after deductible up to a combined lifetime maximum of \$30,000 for physical, speech and occupational therapy
<b>Substance Abuse Treatment (Inpatient)</b>	80% after deductible to a maximum of 15 days per person per calendar year	80% after deductible to a maximum of 15 days per person per calendar year
<b>Substance Abuse Treatment (Outpatient)</b>	100% after \$10 copay to a maximum of \$500 per person per calendar year. Maximum of two lifetime occurrences per person	80% after deductible to a maximum of \$500 per person per calendar year. Maximum of two lifetime occurrences per person
<b>Surgeon's Expenses</b>	100% of PPO fee schedule otherwise subject to R&C charges	80% of R&C charges after deductible
<b>Temporomandibular Joint Disorders (TMJ)</b>	Not covered	

## GLOSSARY OF TERMS

This section defines some of the terms used in this document. Please take the time to read these terms carefully. They will help you to better understand your benefits. Also, in order for benefits to be payable, the expenses must meet the requirements of these terms.

**Ambulatory Surgical Facility** means an establishment licensed as such by the state with an organized medical staff of physicians with permanent facilities that are equipped and operated primarily for the purpose of performing surgical procedures and continuous physician services and registered professional nursing services whenever a patient is in the facility.

**Coinurance** – Once you satisfy the calendar year deductible, depending on the type of service you receive, the Fund may pay a portion of the benefit. The remainder is your share, or coinsurance amount. Refer to the Schedule of Benefits, beginning on page 71, for specific coinsurance information.

**Copayment** – A copayment is a fixed dollar amount that you pay for certain services that are covered under the Plan. For example, doctor's office visits in the PPO network for Plan 1 require a \$10 copayment.

**Covered Medical Expenses** means expenses for medical (including prescription drug, vision, hearing and mental health/substance abuse) and/or dental services or supplies, but only to the extent that:

- they are Medically Necessary, as defined in this Definitions chapter of the document; and
- the charges for them are the negotiated fees for in-network services or the Reasonable and Customary Charges for out-of-network services; and
- coverage for the services or supplies is not excluded, as provided in the General Exclusions Section; and
- the charges do not exceed the calendar year maximum, lifetime maximum or the Plan's individual lifetime maximum benefit.

**Custodial Services** means any services that are not intended primarily to treat a specific injury or sickness (including mental illness, alcohol or drug abuse). Custodial Services include, but are not limited to:

- Services related to watching or protecting a person;

- Services related to performing or assisting a person in performing any activities of daily living, such as walking, grooming, bathing, dressing, getting in or out of bed, toileting, eating, preparing foods or taking medications that can be self-administered; and
- Services not required to be performed by trained or skilled medical or paramedical personnel.

**Deductible** – The deductible is the amount you (and/or your family) must pay in medical expenses before the Fund will begin to pay benefits. The amount of your calendar year deductible depends on the Plan of Benefits you're covered under.

**Eligible Dependent** – The term "dependent" means (1) your lawful spouse; (2) your unmarried children (including a legally adopted child) who are under 19 years of age; (3) your unmarried children who are 19 through 23 years of age and who are enrolled as full-time students in an accredited school, college or university, not employed on a full-time basis and dependent upon you for financial support.

**IMPORTANT:** You are required to furnish the following documentation for dependent coverage if you have not already done so:

1. Marriage certificate;
2. Birth certificate document showing both parents' names, court document or written statement on letterhead from appropriate governmental agency showing legal guardianship and date of birth of each child;
3. Divorce decree if applicable;
4. Proof of a dependent child's attendance at an accredited school or college as a full-time student upon attainment of age 19 must be submitted to the Fund Office twice each year as directed by the Fund Office on an original form which contains the accredited institution's seal.

The term "child" also includes a stepchild or foster child provided the child depends upon you for support and maintenance and has been reported to the Fund Office. See page 8 for details.

If an unmarried dependent child is incapable of self-sustaining employment because of physical handicap or mental retardation and he is dependent upon you for support and maintenance, his coverage will be continued provided his incapability commenced prior to attaining age 19 or age 24 if a full-time student. You must submit proof of your dependent child's incapability to the Fund Office on the later of 31 days after the date he attains 19 years of age or age 24 if a full-time student or 31 days after you are notified of his eligibility. Contact the Fund Office for an application.

Proof of the continued existence of such incapability shall be furnished to the Fund Office from time to time at its request.

**Emergency Treatment** means treatment for an injury or sudden serious illness that poses an urgent or pressing need and is treated within hours of the commencement of the illness or injury.

**Experimental Treatment/Procedure** means a treatment or procedure performed to demonstrate a known truth, examine the validity of a hypothesis, to determine the efficacy of something previously untried or which has not been proven.

**Extended Care Facility** means an institution or a distinct part of an institution which

- is operated pursuant to law and is primarily engaged in providing, for compensation from its patients, skilled nursing care for patients who require medical care because of injury or sickness;
- provides 24-hour-a-day nursing service under the supervision of a full-time employee who is either a doctor or a registered nurse;
- maintains clinical records on all patients;
- provides for having a doctor available to furnish necessary medical care in case of emergency; and
- provides appropriate methods and procedures for the dispensing and administering of drugs and biologicals.

In no event shall "Extended Care Facility" include any institution or part of an institution which is a hospital or which is primarily for the care of mental illness, drug addiction, alcoholism or tuberculosis or which is primarily engaged in providing domiciliary, custodial or educational care or care for the aged.

**Home Health Aide** means a person who provides care of a medical or therapeutic nature and reports to and is under the direct supervision of a Home Health Care Agency.

**Home Health Care Agency** means an agency or organization (or a distinct part of) which:

- is primarily engaged in providing skilled nursing and other therapeutic services for and in the private residence of participants recovering from an injury or sickness;
- is properly licensed or approved according to any applicable state or local standards and is federally certified as a Home Health Care Agency;
- is operated according to policies established by a professional staff including at least one physician and at least one registered nurse;
- provides for supervision of its services by a physician or a registered nurse;
- maintains medical records for all patients.

**Hospital** - The term "hospital" means an institution operated pursuant to law which is primarily engaged in providing for compensation from its patients medical, surgical and diagnostic facilities for the care and treatment of sick and injured persons on an in-patient basis and which provides such facilities under the supervision of a staff of physicians and with 24-hour-a-day nursing services by registered graduate nurses. Unless it meets this definition, the term "hospital" shall not include any institution or part thereof which is used principally as a rest facility, nursing facility, convalescent facility or facility for the aged. A licensed institution used principally for the care and treatment of alcoholics will be included under the definition of "hospital" with the applicable coverage in accordance with the schedule of benefits for which you or a family member are eligible for confinement in such institution. A licensed institution used principally for the care and treatment of mental illness will be included under the definition of "hospital" with the applicable coverage for

confinement in such institution in accordance with the schedule of benefits for which you or a family member are eligible.

**Hospital Charges, Surgical Charges and Medical Charges** – The term “hospital charges” means the charges for covered medical expenses, which are:

- made by a legally constituted hospital for board and room and for other hospital services and supplies (but not including charges for special nursing services or for services for physicians or surgeons) furnished by the hospital during confinement;
- The term “surgical charges” means the charges for covered medical expenses for surgery and for necessary post-operative treatment in connection with the surgery.
- The term “medical charges” means those charges for covered medical expenses that are other than hospital charges or surgical charges as defined above.

**Hospital Confinement** – The term “period of hospital confinement” includes successive periods of hospital confinement for the same or a related disease or bodily injury unless separated by complete recovery from the disease or bodily injury which caused the previous period of hospital confinement or, in the case of the Member, a return to active work for at least one day.

**Hospice Care Facility** means an institution that provides care and service for terminally ill persons and which:

- a. provides 24-hour-a-day nursing care for the terminally ill person with the necessary physical, psychological and spiritual needs, with acute inpatient and outpatient care, home care, bereavement counseling directly or indirectly;
- b. has a medical director who is a physician;
- c. has an interdisciplinary team that coordinates the care and services it provides and which includes at least one physician, one registered professional nurse and one social worker;
- d. maintains central clinical records on all patients; and
- e. is licensed or accredited as a Hospice if required.

**Medically Necessary** means any service, supply, treatment or hospital confinement (or part of a hospital confinement) which is essential to the treatment of the injury or illness for which it is prescribed or performed, meets generally accepted standards of medical practice and is ordered by a physician. The fact that a Physician or other provider may prescribe, order, recommend, or approve a service or supply does not, of itself, make it Medically Necessary or make the expense a Covered Charge.

**Physician** means a licensed medical practitioner who is practicing within the scope of his license and who is licensed to diagnose, prescribe and administer drugs or to perform surgery. It will also include any other licensed medical practitioner whose services are required to be covered by law in the locality where the policy is issued if he is:

- operating within the scope of his license, and
- performing a service for which benefits are provided under this plan when performed by a physician.

**Reasonable and Customary Charges** – The term “reasonable and customary” means the amount normally charged for similar services and supplies which does not exceed the amount ordinarily charged for comparable services and supplies in the locality where the services or supplies are received.

# NEW ENGLAND CARPENTERS HEALTH BENEFITS FUND PRIVACY NOTICE

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## SECTION 1: PURPOSE OF THIS NOTICE AND EFFECTIVE DATE

THIS NOTICE DESCRIBES HOW MEDICAL INFORMATION ABOUT YOU MAY BE USED AND DISCLOSED AND HOW YOU CAN GET ACCESS TO THIS INFORMATION. PLEASE REVIEW IT CAREFULLY.

*This Privacy Notice applies to the Fund Office of the New England Carpenters Health Benefits Fund ("the Fund") and the services that the Fund provides through Hines & Associates, CCN, Delta Dental, Ullicare Rx/Medco., Davis Vision and other business associates of the Fund. The Fund's insurers will send you a notice of their privacy practices separately.*

### Effective date.

The effective date of this Notice is April 14, 2003.

### This Notice is required by law.

The Fund is required by law to take reasonable steps to ensure the privacy of your personally identifiable health information and to inform you about:

1. The Fund's uses and disclosures of Protected Health Information (PHI),
2. Your rights to privacy with respect to your PHI,
3. The Fund's duties with respect to your PHI,
4. Your right to file a complaint with the Fund and with the Secretary of the United States Department of Health and Human Services (HHS), and
5. The person or office you should contact for further information about the Fund's privacy practices.

## SECTION 2: YOUR PROTECTED HEALTH INFORMATION

### Protected Health Information (PHI) Defined

The term "Protected Health Information" (PHI) includes all individually identifiable health information related to your past, present or future physical or mental health condition or to payment for health care. PHI includes information maintained by the Fund in oral, written, or electronic form.

### When the Fund May Disclose Your PHI

Under the law, the Fund may disclose your PHI without your consent or authorization, or the opportunity to agree or object, in the following cases:

- For treatment, payment or health care operations. The Fund and its business associates will use PHI in order to carry out:
  1. Treatment,
  2. Payment, or
  3. Health care operations.

*Treatment* is the provision, coordination or management of health care and related services. It also includes but is not limited to consultations and referrals between one or more of your providers.

For example, the Fund may disclose to a treating orthodontist the name of your treating dentist so that the orthodontist may ask for your dental x-rays from the treating dentist.

*Payment* includes but is not limited to actions to make coverage determinations and payment (including billing, claims management, subrogation, Fund reimbursement, reviews for medical necessity and appropriateness of care and utilization review and preauthorizations).

For example, the Fund may tell a doctor whether you are eligible for coverage or what percentage of the bill will be paid by the Fund. If we contract with third parties to help us with payment operations, such as a physician that reviews medical claims, we will also disclose information

to them. These third parties are known as "business associates."

*Health care operations* includes but is not limited to quality assessment and improvement, reviewing competence or qualifications of health care professionals, underwriting, premium rating and other insurance activities relating to creating or renewing insurance contracts. It also includes disease management, case management, conducting or arranging for medical review, legal services, and auditing functions including fraud and abuse compliance programs, business planning and development, business management and general administrative activities.

For example, the Fund may use information about your claims to refer into a disease management program, a well-pregnancy program, project future benefit costs or audit the accuracy of its claims processing functions.

- **Disclosure to the Fund's Trustees**

The Fund will also disclose PHI to the Fund Sponsor, which is the Board of Trustees of the New England Carpenters Health Benefits Fund, for purposes related to treatment, payment, and health care operations, and has amended the Plan Document to permit this use and disclosure as required by federal law. For example, we may disclose information to the Board of Trustees to allow them to decide an appeal or review a subrogation claim.

- In addition, the Fund may disclose "summary health information" to the Board of Trustees for obtaining premium bids or modifying, amending or terminating the Fund's group health plan. Summary information summarizes the claims history, claims expenses or type of claims experience by individuals for whom a Plan Sponsor such as the Board of Trustees has provided health benefits under a group health plan. Identifying information will be deleted from summary health information, in accordance with federal privacy rules.

- **At your request.** If you request it, the Fund is required to give you access to certain PHI in order to allow you to inspect and/or copy it.
- **When required by applicable law.**
- **As required by HHS.** The Secretary of the United States Department of Health and Human Services may require the disclosure of your PHI to investigate or determine the Fund's compliance with the privacy regulations.
- **Public health purposes.** To an authorized public health authority if required by law or for public health and safety purposes. PHI may also be used or disclosed if you have been exposed to a communicable disease or are at risk of spreading a disease or condition, if authorized by law.
- **Domestic violence or abuse situations.** When authorized by law to report information about abuse, neglect or domestic violence to public authorities if a reasonable belief exists that you may be a victim of abuse, neglect or domestic violence. In such case, the Fund will promptly inform you that such a disclosure has been or will be made unless that notice would cause a risk of serious harm.
- **Health oversight activities.** To a health oversight agency for oversight activities authorized by law. These activities include civil, administrative or criminal investigations, inspections, licensure or disciplinary actions (for example, to investigate complaints against health care providers) and other activities necessary for appropriate oversight of government benefit programs (for example, to the Department of Labor).
- **Legal proceedings.** When required for judicial or administrative proceedings. For example, your PHI may be disclosed in response to a subpoena or discovery request that is accompanied by a court order.
- **Law enforcement health purposes.** When required for law enforcement purposes (for example, to report certain types of wounds).



- **Law enforcement emergency purposes.** For certain law enforcement purposes, including:
  1. identifying or locating a suspect, fugitive, material witness or missing person, and
  2. disclosing information about an individual who is or is suspected to be a victim of a crime.
- **Determining cause of death and organ donation.** When required to be given to a coroner or medical examiner to identify a deceased person, determine a cause of death or other authorized duties. We may also disclose PHI for cadaveric organ, eye or tissue donation purposes.
- **Funeral purposes.** When required to be given to funeral directors to carry out their duties with respect to the decedent.
- **Research.** For research, subject to certain conditions.
- **Health or safety threats.** When, consistent with applicable law and standards of ethical conduct, the Fund in good faith believes the use or disclosure is necessary to prevent or lessen a serious and imminent threat to the health or safety of a person or the public and the disclosure is to a person reasonably able to prevent or lessen the threat, including the target of the threat.
- **Workers' compensation programs.** When authorized by and to the extent necessary to comply with workers' compensation or other similar programs established by law.
- **Specialized Government Functions.** When required, to military authorities under certain circumstances, or to authorized federal officials for lawful intelligence, counter intelligence and other national security activities.

Except as otherwise indicated in this notice, uses and disclosures will be made only with your written authorization subject to your right to revoke your authorization.

#### **When the Disclosure of Your PHI Requires Your Written Authorization**

Although the Fund does not routinely obtain psychotherapy notes, it must generally obtain your written authorization before the Fund will use or disclose psychotherapy notes about you. However, the Fund may use and disclose such notes when needed by the Fund to defend itself against litigation filed by you.

Psychotherapy notes are separately filed notes about your conversations with your mental health professional during a counseling session. They do not include summary information about your mental health treatment.

The Fund may provide health information for the purpose of evaluating and processing a claim for disability benefits or to process a hardship loan from the Annuity Fund; however, the Fund will obtain your written authorization before it will use or disclose any health information for this purpose.

#### **When You Can Object and Prevent the Fund from Using or Disclosing PHI**

Disclosure of your PHI to family members, other relatives, your close personal friends and any other person you choose is allowed under federal law if:

- The information is directly relevant to the family or friend's involvement with your care or payment for that care, and
- You have either agreed to the disclosure or have been given an opportunity to object and have not objected.

#### **Other Uses or Disclosures**

The Fund may contact you to provide you with information about treatment alternatives or other health-related benefits and services that may be of interest to you.

**SECTION 3: YOUR INDIVIDUAL PRIVACY RIGHTS****You May Request Restrictions on PHI Uses and Disclosures**

You may request the Fund to:

1. Restrict the uses and disclosures of your PHI to carry out treatment, payment or health care operations, or
2. Restrict uses and disclosures to family members, relatives, friends or other persons identified by you who are involved in your care.

The Fund, however, is not required to agree to your request.

You or your personal representative will be required to complete a form to request restrictions on uses and disclosures of your PHI. Make such requests to the Privacy Official at:

The New England Carpenters Health Benefits Fund  
350 Fordham Road  
Wilmington, MA 01887  
Phone: (800) 344-1515

**You May Request Confidential Communications**

The Fund will accommodate an individual's reasonable request to receive communications of PHI by alternative means or at alternative locations where the request includes a statement that disclosure could endanger the individual.

You or your personal representative will be required to complete a form to request restrictions on uses and disclosures of your PHI. Make such requests to the Privacy Official (at the address listed above).

**You May Inspect and Copy PHI**

You have a right to inspect and obtain a copy of your PHI contained in a "designated record set," for as long as the Fund maintains the PHI.

The Fund must provide the requested information within 30 days if the information is maintained on site or within 60 days if the information is maintained offsite. A single 30-day extension is

allowed if the Fund is unable to comply with the deadline.

You or your personal representative will be required to complete a form to request access to the PHI. A reasonable fee may be charged. Requests for access to PHI should be made to the Privacy Official (at the address listed at left).

If access is denied, you or your personal representative will be provided with a written denial setting forth the basis for the denial, a description of how you may exercise your review rights and a description of how you may complain to the Fund and HHS.

**Designated Record Set:** includes your medical records and billing records that are maintained by or for a covered health care provider. Records include enrollment, payment, billing, claims adjudication and case or medical management record systems maintained by or for a health plan or other information used in whole or in part by or for the covered entity to make decisions about you. Information used for quality control or peer review analyses and not used to make decisions about you is not included.

**You Have the Right to Amend Your PHI**

You have the right to request that the Fund amend your PHI or a record about you in a designated record set for as long as the PHI is maintained in the designated record set subject to certain expectations. See the Fund's Right to Amend Policy (available on request from the Fund's Privacy Official) for a list of exceptions.

The Fund has 60 days after receiving your request to act on it. The Fund is allowed a single 30-day extension if the Fund is unable to comply with the 60-day deadline. If the Fund denied your request in whole or part, the Fund must provide you with a written denial that explains the basis for the decision. You or your personal representative may then submit a written statement disagreeing with the denial and have that statement included with any future disclosures of that PHI.



You should make your request to amend PHI to the Privacy Official (at the address listed above). You or your personal representative will be required to complete a form to request amendment of the PHI.

**You Have the Right to Receive an Accounting of the Fund's PHI Disclosures**

At your request, the Fund will also provide you with an accounting of certain disclosures by the Fund of your PHI. We do not have to provide you with an accounting of disclosures related to treatment, payment, or health care operations, or disclosures made to you or authorized by you in writing. See the Fund's Accounting for Disclosure Policy (available on request from the Fund's Privacy Official) for the complete list of disclosures for which an accounting is not required.

The Fund has 60 days to provide the accounting. The Fund is allowed an additional 30 days if the Fund gives you a written statement of the reasons for the delay and the date by which the accounting will be provided.

If you request more than one accounting within a 12-month period, the Fund may charge a reasonable, cost-based fee for each subsequent accounting.

**You Have the Right to Receive a Paper Copy of This Notice Upon Request**

To obtain a paper copy of this Notice, contact the Privacy Official (at the address listed above).

**Your Personal Representative**

You may exercise your rights through a personal representative who will be required to produce evidence of authority to act on your behalf before the personal representative will be given access to your PHI or be allowed to take any action for you. Proof of such authority will be a completed, signed and approved Appointment of Personal Representative form. You may obtain this form by calling the Fund Office.

The Fund retains discretion to deny access to your PHI to a personal representative to provide protection to those vulnerable people who depend on others to

exercise their rights under these rules and who may be subject to abuse or neglect.

The Fund will recognize certain individuals as personal representatives without you having to complete an Appointment of Personal Representative form. For example, the Fund will automatically consider a spouse, parent of a Member, or an adult child (age 18 or over) of a Member to be the personal representative of an individual covered by the Fund. In addition, the Fund will consider a parent or guardian as the personal representative of an unemancipated minor except in a few types of situations. A spouse, a parent, or child may act on an individual's behalf, including requesting access to their PHI. Spouses and unemancipated minors may, however, request that the Fund restrict information that goes to family members as described above at the beginning of Section 3 of this Notice.

You should also review the Fund's Policy and Procedure for the Recognition of Personal Representatives (available upon request from the Fund's Privacy Official) for a more complete description of the circumstances where the Fund will automatically consider an individual to be a personal representative for purposes of exercising your rights under this Privacy Notice.

**SECTION 4: THE FUND'S DUTIES****Maintaining Your Privacy**

The Fund is required by law to maintain the privacy of your PHI and to provide you with notice of its legal duties and privacy practices.

This notice is effective beginning on April 14, 2003 and the Fund is required to comply with the terms of this notice. However, the Fund reserves the right to change its privacy practices and to apply the changes to any PHI received or maintained by the Fund prior to that date. If a privacy practice is changed, a revised version of this notice will be provided to you and to all past and present participants and beneficiaries for whom the Fund still maintains PHI.

The Privacy Notice will be provided by first class mail to all named participants. Any other person, including dependents of named participants, may receive a copy upon request.

Any revised version of this notice will be distributed within 60 days of the effective date of any material change to:

1. The uses or disclosures of PHI,
2. Your individual rights,
3. The duties of the Fund, or
4. Other privacy practices stated in this notice.

**Disclosing Only the Minimum Necessary Protected Health Information**

When using or disclosing PHI or when requesting PHI from another covered entity, the Fund will make reasonable efforts not to use, disclose or request more than the minimum amount of PHI necessary to accomplish the intended purpose of the use, disclosure or request, taking into consideration practical and technological limitations.

However, the minimum necessary standard will not apply in the following situations:

1. Disclosures to or requests made by a health care provider for treatment,

2. Uses or disclosures made to you,
3. Uses or disclosures made pursuant to your written authorization,
4. Disclosures made to the Secretary of the United States Department of Health and Human Services pursuant to its enforcement activities under HIPAA,
5. Uses or disclosures required by law, and
6. Uses or disclosures required for the Fund's compliance with the HIPAA privacy regulations.

This notice does not apply to information that has been de-identified. De-identified information is information that:

1. Does not identify you, and
2. With respect to which there is not reasonable basis to believe that the information can be used to identify you.

**SECTION 5: YOUR RIGHT TO FILE A COMPLAINT WITH THE FUND OR THE HHS SECRETARY**

If you believe that your privacy rights have been violated, you may file a complaint with the Fund in care of the Privacy Official (at the address listed above).

You may also file a complaint with the Secretary of the U.S. Department of Health and Human Services ("HHS"). Please contact the nearest office of the Department of Health and Human Services, listed in your telephone directory, visit the HHS website at [www.hhs.gov](http://www.hhs.gov), or call the Privacy Official for more information about how to file a complaint.

The Fund will not retaliate against you for filing a complaint.

**SECTION 6: IF YOU NEED MORE INFORMATION**

If you have any questions regarding this notice or the subjects addressed in it, you may contact the Privacy Official at the Fund Office.

#### **SECTION 7: CONCLUSION**

PHI use and disclosure by the Fund is regulated by the federal Health Insurance Portability and Accountability Act, known as HIPAA. You may find these rules at 45 Code of Federal Regulations Parts 160 and 164. This notice attempts to summarize the regulations. The regulations will supersede this notice if there is any discrepancy between the information in this notice and the regulations.

## BOARD OF TRUSTEES

### Employer Trustees

William J. Sullivan, Secretary/Treasurer  
Daniel O'Connell's Sons, Inc.  
480 Hampden Street  
P.O. Box 267  
Holyoke, MA 01041

Stephan A. Adamic  
Co-Secretary/Treasurer  
P.O. Box 302  
Grantham, NH 03753

George M. Bidgood  
Bidgood Associates, Inc.  
99 Essex Street  
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## NOTES

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**CARP-00188**



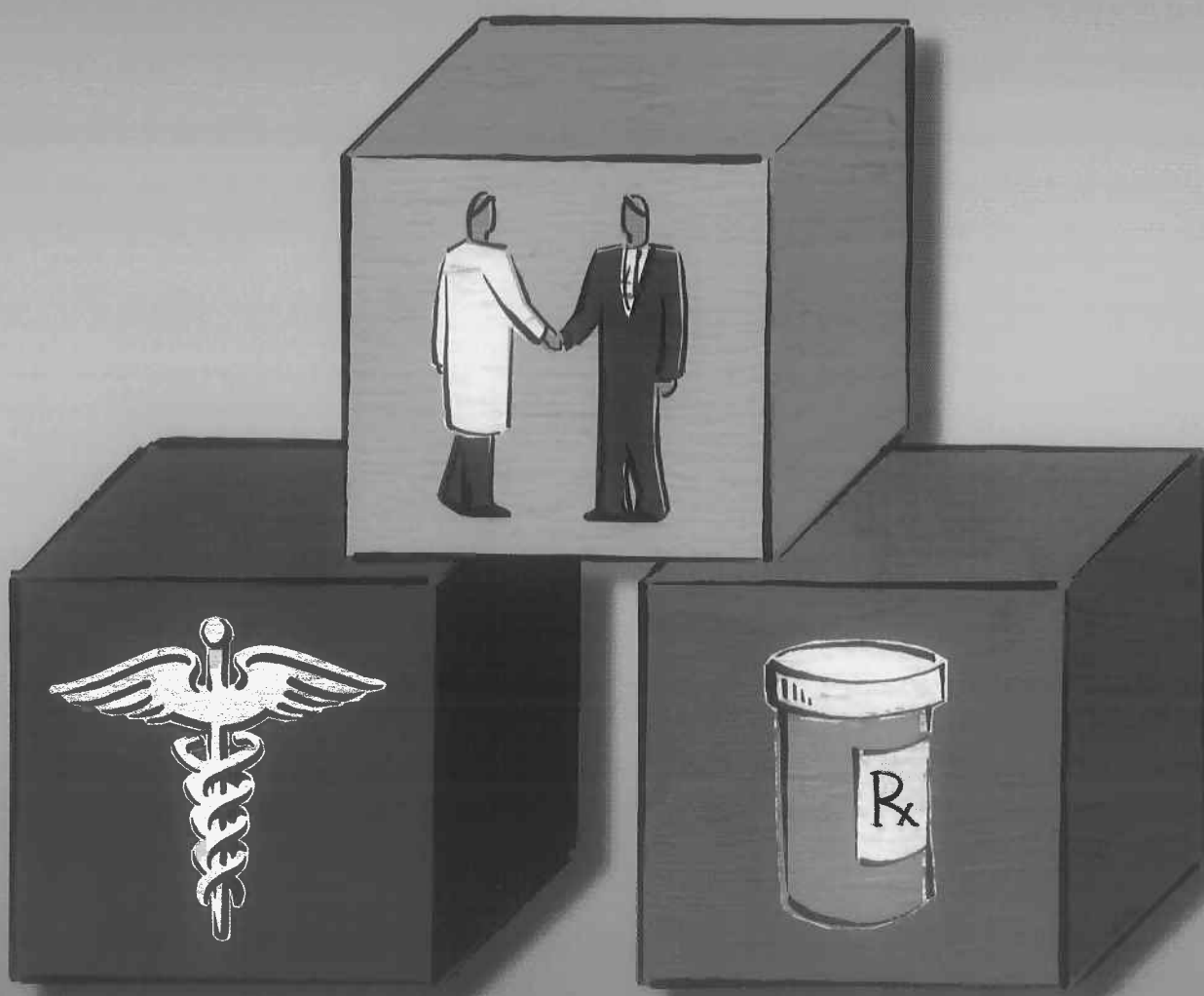
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PROVIDED BY TAKEDA

# THE PRESCRIPTION DRUG BENEFIT COST AND PLAN DESIGN SURVEY REPORT

2004 EDITION



Creating Opportunities With Healthcare Solutions



Dear Health Professional:

Takeda Pharmaceuticals North America, Inc. is pleased to present you with the 2004 *Prescription Drug Benefit Cost and Plan Design Survey Report*. Conducted annually by the Pharmacy Benefit Management Institute, Inc., the report is based on data collected from 403 employers (representing approximately 11 million beneficiaries). This information provides you with a comprehensive overview of prescription drug coverage, utilization, and costs. In addition, we hope you will garner a greater understanding of the current management trends and issues in pharmacy benefit design.

We value our relationships with healthcare leaders and strive to provide quality products and services to help meet your needs. We hope you find the information in this report useful to your organization. As always, we measure our success based on your success.

Sincerely,

A handwritten signature in black ink, appearing to read "S. Shockley".

Steve Shockley

National Director of Managed Care Markets  
Takeda Pharmaceuticals North America, Inc.



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Dear Reader:

A year has gone by since Takeda published the last Prescription Drug Benefit Cost and Plan Design Survey report. NBCH's letter in that report focused on the business case for disease management. No doubt, there is proof that strategies for improving health care outcomes have been put to the test and have passed. Members of the National Business Coalition on Health shared their success stories, ranging from South Central Michigan Health Alliance's safety and quality project to prevent errors in the outpatient pharmacy setting, to a state chronic data clearinghouse for asthma and diabetes spear-headed by the Oregon Coalition of Health Care Purchasers.



Andrew Webber

This year, it is difficult to avoid what is starting to look like a pharmacy battleground, pitting purchasers and payers against PBMs. Although the PBM industry has earned praise for saving money, increasing compliance and improving quality, and deservedly so, its reputation is taking a beating. The federal government, various states, and a number of private parties are suing PBMs. PBMs are being sued about drug switching practices, fiduciary matters, and a variety of pricing issues.

These cases have reinforced the need for transparency—informing consumers, payers, and purchasers of net prescription costs. Because of the litigation and proposed legislation, PBMs are reinventing their business models.

Although transparency has more than one definition, most plan sponsors consider it a solution to the lack of information about the flow of money from the manufacturer to the PBM. Without transparency and disclosure, plan sponsors cannot make informed decisions about establishing formularies and which drugs to promote to their employees/members.

Christopher V. Goff, J.D., president/CEO of Employers Health Purchasing Corporation of Ohio (EHPCO) in Canton, Ohio, says that payers will be concerned about their PBM relationships until incentives between insurers/plan sponsors and PBMs are aligned. Payers do not know how PBMs make their money and what drugs really cost.

This past February, EHPCO, the Florida Health Care Coalition and Corporate United, a procurement consortium, joined forces in a request for proposal process, asking eight PBMs to respond with two models for PBM contracting—one a traditional model and the other providing transparency and disclosure for self-insured employers.

Besides seeking transparency and full disclosure, the goals of the RFP were to examine direct contracting with manufacturers compared to receiving downstream rebates via a PBM; active engagement in the process to determine preferred and non-preferred status of drugs; utilize sourcing technology; improve discounts, rebates and dispensing fees; and examine clinical programs to evaluate savings calculation methodologies and payment provisions.

Embedded in the RFP was a request to perform a drug mix analysis of 17 therapeutic classes, representing 50 percent of EHPCO's drug spend. The coalition asked each PBM to disclose their market share for drugs on their formularies in each class, both for retail and mail, to determine projected net costs based on formulary effectiveness with discounts, rebates, dispensing and administrative fees applied. The goal, Goff says, was to determine whether preferring higher cost drugs

resulted in lower net costs for plan sponsors because of the associated rebates. Goff cautioned that plan sponsors all too often make the mistake of simply focusing on higher rebates rather than focusing on the net unit prescription cost.

When the results came in, EHPCO retained its current PBM. The new contract will save more than \$20 million annually on pharmacy costs for EHPCO's 400,000 lives, with employer savings of 6% to 18%. Since EHPCO experienced a gross spend in 2003 of \$319.4 million, the savings are notable. EHPCO will share its RFP process with other members of NBCH this summer.

NBCH's members are trying different strategies to align incentives among all stakeholders and if possible to move closer to solving the lack of transparency problem. Over the past few years, the Heartland Healthcare Coalition has seen a rapid shifting to a three-tiered pharmacy benefit structure; transition back to co-insurance; and wider differentials between preferred and non-preferred brand drug copayments or co-insurance among its 46 employers members. They represent about 365,000 covered lives in manufacturing, service industries, government, health care, and education throughout central and southern Illinois and eastern Iowa.

Jerry Custer, the coalition's executive director, says members are paying more attention to transparency and full disclosure issues, an interest prompted by educational materials and programs made available to them. He expects employers to demand transparency and full disclosure from their PBMs when they renew their agreements. Custer recommends that employers ask for: 1) the ability to audit PBM financial information, including rebate calculations and invoices from retail pharmacies; 2) detailed information on network oversight, such as reporting verifiable fraud occurrences; and 3) identification of drug switches, if any, that may influence employer cost or patient safety.

The Piedmont Health Coalition in Burlington, N.C. tweaked its pharmacy benefit design four years ago and now offers a three-tiered structure. Gregory Walters, the coalition's president, says the nine-employer group is considering moving to five tiers — generics, special products chosen by employers for certain disease states, preferred brands, non-preferred brands and specialty or uncovered medications, such as lifestyle drugs. According to Walters, even though lifestyle drugs may be restricted or not covered, their availability gives employees more choice, one of the advantages to a five-tiered structure he says.

Walters says Piedmont is too small to exert any leverage in demanding transparency and full disclosure but anticipates collaborating with similar organizations to support national contracting standards.

The Georgia Healthcare Leadership Council, headquartered in Atlanta, is targeting two specific areas in its pharmacy benefits—workers compensation and biotech drugs. James Purcell, the council's president, says the group, which does not yet purchase pharmaceuticals as a coalition, is developing a fixed formulary for drugs commonly used in the treatment of industrial and occupational accidents and guaranteeing the retailer payment for first fill. The council plans to utilize a sub-PBM specializing in biotech drugs and injectables to staunch the exploding spend of these drugs.

With all of the ranting and raving about the lack of transparency by PBMs, Barbara Belovich, executive director of the Health Action Council of Northeast Ohio, praises PBMs for keeping the drug trend low. "We know they make money, but we want them to do good things, which they do," she said.

The Health Action Council's 40 employer members, representing 400,000 lives, is focusing on providing tools to enrollees to compare drug prices, urging them to discuss generic alternatives with their physicians, and creating copayment differentials to encourage the use of lower cost drugs.



Jack Mahoney, MD, corporate medical director of Pitney Bowes, is well aware of the challenges of developing pharmacy benefits. To promote the care of chronic disease, the company decided to place all medications for asthma, diabetes, and hypertension in the lowest cost-sharing tier. This design removes financial barriers, which may prevent patients from continuing their treatment regimens. This move was prompted in part by a new study by the RAND Corporation, which confirms that when the amount that a consumer is required to pay for a prescription drugs doubles in cost, the consumer will respond by cutting their use of common drugs for chronic diseases by as much as 23 percent.

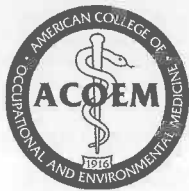
When we talk about transparency, we also need to talk about information provided to enrollees about the cost of drugs. Arnold Milstein, national health care thought leader for William M. Mercer and medical director for the Pacific Business Group on Health based in San Francisco, reminds us that all stakeholders need information on the effectiveness of drug options in treating a patient and their cost.

To empower health care consumers, enrollees should have a comparison of therapeutically equivalent drugs, their effectiveness, and how much their choices will cost. If plan design appropriately creates an incentive for enrollees, they can make selections that are not only in their best interest but also in the best interest of the group.

Sincerely,

A handwritten signature in cursive script, reading "Andrew Webber".

Andrew Webber  
President & CEO



## AMERICAN COLLEGE OF OCCUPATIONAL AND ENVIRONMENTAL MEDICINE

Dear Reader:

On behalf of the American College of Occupational and Environmental Medicine (ACOEM), I am pleased to serve as Co-Chair for the Prescription Drug Benefit Cost and Plan Design Survey Report provided by Takeda. ACOEM is the nation's largest medical society dedicated to promoting the health of workers through preventive medicine, clinical care, research, and education. The College represents occupational and environmental physicians who work in private practice, corporations, academia, hospitals, government, and the military. ACOEM provides leadership to promote optimal health



Barry S. Eisenberg

and safety of workers, workplaces, and environments by educating health professionals and the public, stimulating research, enhancing the quality of practice, guiding public policy, and advancing the field of occupational and environmental medicine. ACOEM members are knowledgeable and skilled in treating job-related diseases, recognizing and resolving workplace hazards, instituting rehabilitation methods, and providing well-managed care.

As you know, in this era of downsizing and corporate instability, there is increased stress and pressures on employees resulting in workplace injury and illness and affecting overall employee productivity. Many American companies are responding to these pressures and striving to provide safer and healthier workplaces. To assist them, ACOEM offers many initiatives that focus on improving employee health, wellness, and productivity through disease management, which may include the appropriate use of pharmacologic agents. This emphasis on workplace health recognizes and supports the national focus on healthier lifestyles. For example, promoting the treatment and management of chronic medical conditions such as asthma, diabetes, and high blood pressure through workplace programs can translate to increased productivity, enhanced job satisfaction, and stronger bottom-line results.

The ACOEM's Corporate Health Achievement Award recognizes organizations that promote healthier workers and provide workplace health, wellness, and safety programs. Model practices of past recipients have included:

- Development of on-site ambulatory health clinics for employees that treats both work and non-work related illnesses and injuries and include in many cases, dispensing free prescription medications. This program has resulted in less time away from work and a venue for the treatment for minor illnesses.
- Development of an international travel program that provides employees with travel medicine kits for their overseas business and personal trips.
- Establishment of an ergonomic program, which incorporates a review of each employee's worksite and identification of appropriate exercise. If an injury occurs, there is a conservative therapy approach including nocturnal wrist splints, anti-inflammatory medications, and physical therapy. Since introduction of the ergonomic program, the surgical intervention rate has been sharply reduced.

To view other innovative programs at the worksite, visit <http://www.chaa.org>.

In addition to identifying the best "Corporate Practices," ACOEM is involved in research to better understand the changing environment in the business world. To that end, ACOEM and The Benfield Group conducted a survey of Corporate Medical Directors (CMDs) and found that CMDs' influence over health benefit decisions is expanding, and that CMDs have a grip on the health services delivery decisions that falls under the traditional domain of occupational health. Many, but still a minority, of CMDs have significant input into disability insurance, group health, and pharmacy programs. CMDs who have been successful in championing health and productivity management (HPM) in their organizations are

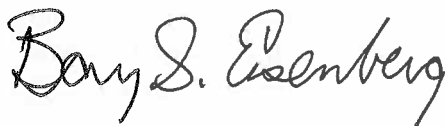
finding that the HPM platform leads to new levels of authority and influence over a broader range of health benefit decision making. As HPM increasingly becomes the language of large employee benefit consultancies and takes hold among human resource and employee benefits professionals, CMDs with HPM background and knowledge are well positioned to provide meaningful input into benefit design programs. (ACOEM/The Benfield Group, 2003. Strategic Management Needs in Health & Productivity.)

Other ACOEM programs that offer guidance and support to corporate medical directors and businesses include:

- A recent survey on the utilization and impact of Automatic External Defibrillators (AEDs) in the workplace. AEDs are devices that provide electric shock to victims in cardiac arrest. This descriptive survey indicates that companies with programs have found them to be beneficial to their overall health management and have resulted in successful resuscitation efforts. ACOEM is using the survey results to enhance educational programming and resource materials. For further medical and scientific information on AEDs, guidelines for implementing an AED program, and links to other sites with information on AED deployment visit the ACOEM AED webpage at <http://www.acoem.org/aed>.
- Several surveys of corporate medical directors and benefit managers are underway to gain their perspectives on the business value of good health. These surveys will help us better understand the views of corporate medical directors and their colleagues in health benefits and human resources, and will enhance programming for our members. It is anticipated that research findings will result in the development of resource materials on the linkages between medical directors and benefits/human resource personnel and identify how these linkages may be leveraged to maximize employee benefits.
- Course on "Managing the Spectrum of Health and Disease in Employee Populations: The Role of the Corporate Physician in Benefits and Disease Management." This educational course, recently presented at the American Occupational Health Conference, discussed the keys to effective disease management in corporate populations, including program design, implementation, and analysis. The program helps physicians better understand disease management and the entire spectrum of health interventions—from prevention to case management—including providing access to medications for chronic conditions.
- ACOEM, in conjunction with The Benfield Group, is sponsoring regional, educational conferences to address the health care workers low influenza vaccination rates. This has become a significant health issue requiring immediate action on a national, regional, and local level. The conferences, "The Imperative for Improving Health Care Worker Influenza Vaccination Rate," are intended to raise awareness in the local medical and health care professional community about the need to vaccinate all health care workers against influenza and to promote strategies for increasing the number of health care employees who are vaccinated.

Mergers, downsizings, technology explosions, market swings, and demographic shifts provide a complex workplace with a host of issues for employers and employees. However, renewed attention to the health, safety, and wellness needs of employees can result in a stronger, more productive economy. Working together, we can provide the environment to continue growing and thriving in the global marketplace.

Respectfully,



Barry S. Eisenberg, CAE  
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## EXECUTIVE SUMMARY

### INTRODUCTION

The Pharmacy Benefit Management Institute, Inc. has conducted a survey of the nation's employers to assess trends in pharmacy benefit management, plan design, and cost issues every year since 1995. Survey data are collected, compared, and analyzed to provide employers with a comprehensive overview of the current state of prescription drug coverage cost and plan design issues.

Each year, PBMI receives valuable input from respondents that is used to improve the scope of the survey and report. PBMI has expanded this year's report to include discussions about covering over-the-counter (OTC) drugs, mandatory mail service for refills, consumer-directed products, and the impact of Medicare changes on retiree benefits.

### KEY FINDINGS

#### Pharmacy Reimbursement Decreases

Reimbursement for both retail and mail service pharmacy continues to decrease. The average AWP and dispensing fee paid to retail pharmacies for brand drugs is now 85.5% and \$2.05, respectively. Average AWP and dispensing fee paid to mail service pharmacies for brand drugs is now 79.6% and \$0.56, respectively.

#### PBM Administrative Fee Decreases

PBM administrative fees for both retail and mail service also are decreasing. In 2002, the average administrative fee paid for each retail prescription was \$0.28. In 2003, the average administrative fee paid for each retail prescription decreased to \$0.24. The average administrative fee paid per mail service pharmacy claim in 2003 was \$0.15 compared with \$0.16 in 2002.

#### Formulary Use Continues To Rise

The use of formularies continues to increase. In 1995, only 54% of respondents reported using a formulary. This percentage increased to 92% in 2003. The traditional open formulary has been replaced by the incented formulary concept, which has grown from just 25% of respondents in 1999 to 71% in 2003. During this time, the percentage of respondents offering closed formularies decreased from 8% in 1999 to 3% in 2003.

PBMI included a survey question asking the respondents to indicate whether they had requested that their PBM change the formulary status of a drug (e.g., from pre-

ferred status to nonpreferred status). Surprisingly, 16% of the respondents indicated they had requested a change. In follow-up calls to a number of respondents, PBMI learned that most of the requested changes were for simple issues such as moving drugs from one cost-sharing tier to another or excluding preferred drug products. The drug categories mentioned most often in these actions were nonsedating antihistamines and proton pump inhibitors.

#### Plan Sponsors Settling For Fixed Rebate Payments

The respondents are choosing to forgo the potential for higher rebate payments, and the risk of lower rebate payments, by negotiating a fixed rebate amount per claim rather than a percentage of rebates collected. Although equal percentages of respondents (46%) are currently receiving either a fixed amount or a percentage rebate, the percentage of employers receiving the fixed amount has

increased from 33% in 2001 to 46% in 2003. Only 8% receive the greater of the two amounts.

46% OF PLAN SPONSORS  
FORGO POTENTIAL  
FOR HIGHER REBATES  
BY NEGOTIATING  
A FIXED REBATE.

#### Retail, Mail Cost Sharing Moves Upward At Different Rates

Retail copayments increased by 10% or less for all tiers from 2002 to 2003. Mail service copayments, however, increased by more than 10% for all tiers between 2002 and 2003. The average first-tier mail copayment increased by 14%, the second-tier increased by 20%, and the third-tier increased by 11%. Because mail service copayments have increased more quickly than retail copayments for the past few years, the mail service second-tier copayment is now 1.9 times the retail second-tier copayment as compared to 1.6 times in 2001.

The percentage of respondents using coinsurance for second-tier retail cost sharing increased from 26% in 2002 to 30% in 2003. Coinsurance often is used in combination with a minimum and or maximum copayment amount. Some respondents use one or the other and some use both. The average second-tier, minimum copayment for coinsurance plans is \$15.43. Although used less frequently, the average maximum copayment (\$40.70) is more than two times the average minimum copayment for coinsurance plans.

On average, beneficiaries pay about 20% of the cost of their retail prescription for drugs in the first tier, 26% for drugs in the second tier, and 40% for drugs in the third tier. The use of the three-tier copayment structure has



encouraged employers to differentiate the coinsurance percentage among the three categories. Using a higher percentage coinsurance for the third tier increases the incentive to use lower cost, first-tier drugs.

#### **Drug Benefit Costs Increase**

PBMI collects a limited amount of utilization data to quantify the impact of various benefit plan design elements on utilization. Survey respondents reported a 14% increase in costs from 2002 to 2003. The change in costs cannot be compared with changes reported in previous years because the basis for the cost changed from "after-cost-share" dollars in 2002 to "before-cost-share" dollars in 2003. The trend rates reported range from an increase of 65% to a decrease of 7%.

#### **Generic Utilization Increases**

Average retail generic utilization increased from 41.5% in 2002 to 44.1% in 2003. Average mail service generic utilization increased from 31.8% in 2002 to 34.0% in 2003.

#### **Mail Service Use Increases**

Mail service prescriptions as a percentage of all prescriptions increased from 13% in 2002 to 16% in 2003. Mail service utilization almost doubles when mail service is required for maintenance prescriptions from 14% for voluntary use to 27% for mandatory use.

#### **Implications of Findings**

Despite modest declines in pharmacy reimbursement and administrative fees, higher copayments, and increas-

ingly effective benefit management strategies, drug benefit costs continue to climb with double-digit increases.

Unfortunately, although higher drug copayments may reduce drug benefit costs, it may result in higher health care costs.

A RAND Institute study<sup>1</sup> published in a May of 2004 issue of *The Journal of the American Medical Association* quantifies the impact of cost sharing increases on utilization of drugs in several therapeutic classes. Goldman and colleagues make several interesting points. First, higher copayments resulted in lower utilization. Second, patients were less likely to stop using drugs used to treat life-threatening conditions. Third, although higher drug copayments result in less utilization, it also resulted in higher emergency room visits and hospital stays. Finally, reducing or eliminating drug copayments for selected categories such as asthma and diabetes resulted in fewer emergency room visits and hospitalizations.

According to the study, because of the medical expenses associated with ineffective or under treatment of these chronic conditions, plan sponsors must consider economic and clinical outcomes when making funding decisions about drug coverage all of the way down to drug-specific levels. Employees and retirees are not well served by simplistic, one-size-fits-all plan designs. Current research studies continue to point toward the need for evidence-based, health care management.

<sup>1</sup>Goldman, D.P. et al. Pharmacy Benefits and the Use of Drugs by the Chronically Ill. *Journal of the American Medical Association*. 2004: 291(19): 2344-2350.

## METHODOLOGY

This report is based upon data collected during the fall of 2003. The data were collected using a survey designed and conducted by the Pharmacy Benefit Management Institute, Inc. (PBMI). Based in Tempe, Arizona, PBMI provides information and education services to the pharmacy benefit management industry. PBMI analyzed the survey data, wrote, and produced this report. PBMI takes full responsibility for its content.

PBMI gratefully acknowledges the support of Takeda Pharmaceuticals North America, Inc. for the provision of a grant to cover the costs incurred in the production of this report. Takeda Pharmaceuticals North America, Inc. has no access to the individual responses or raw data gathered by this survey nor do any other third parties. This protects the confidentiality of the survey respondents and ensures the independence and objectivity of this report.

PBMI received 403 completed surveys representing approximately 11 million beneficiaries. The number of beneficiaries reported by a respondent is for the benefit plan for which the survey was completed, not necessarily

all of the beneficiaries covered by this respondent for all plans provided.

### Respondent Demographics

The breakdown of respondents according to employer size has remained relatively constant since the inception of this survey. The survey respondents are grouped according to number of members ranging in size from those with 2,000 or fewer members (18%) to those with more than 50,000 members (12%) as illustrated in Table 1.

The composition of the respondents by geographic region is displayed in Figure 1. Respondents with headquarters in the Midwest represent the greatest number of companies (37%) and employers with headquarters in the West have the least (10%).

Employers are assigned to standard industrial classification (SIC) code divisions based on the first two digits of the employer's primary SIC code as illustrated in Table 32 in the Appendix. More than a third (35%) of the respondents are from the services industry. A complete breakdown

Table 1 Respondents Grouped By Number of Members

Number of Members	Employers	Employees	Employee Dependents	Retirees	Retiree Dependents	Total Beneficiaries
Unreported	35	0	0	0	0	0
1 - 2,000	71	35,138	16,295	3,273	756	55,462
2,001 - 4,000	43	64,496	47,415	7,602	1,708	121,221
4,001 - 6,000	44	102,739	101,621	9,509	4,433	218,302
6,001 - 10,000	50	178,632	171,504	20,785	12,401	383,322
10,001 - 20,000	54	335,959	359,892	55,727	26,709	778,287
20,001 - 50,000	59	696,611	895,415	154,342	92,210	1,838,578
50,001 +	47	3,503,631	2,775,877	1,004,919	301,814	7,586,241
Total	403	4,917,206	4,368,019	1,256,157	440,031	10,981,413

Figure 1: Percentage of Respondents By Geographic Location

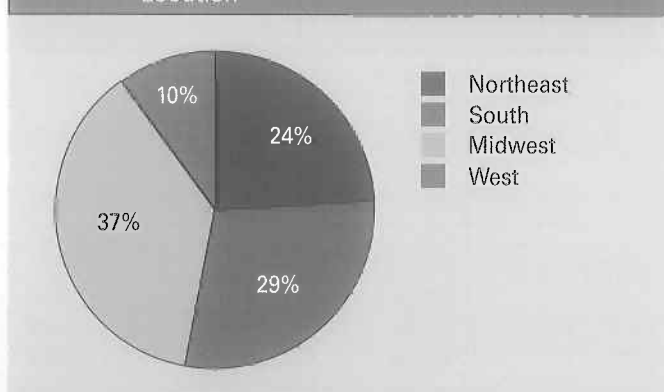
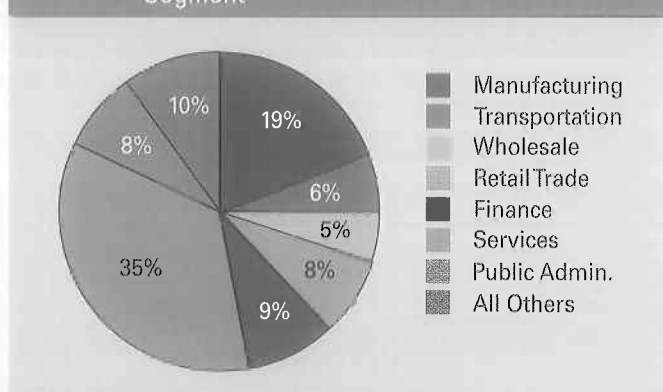


Figure 2: Percentage of Respondents By Industry Segment



by industry segment is shown in Figure 2.

Respondents were asked to specify who has primary responsibility for defining the drug benefit: the employer or another entity such as a managed care organization, health care administrator, or insurer. This information allows evaluation of the differences among benefit designs based on whether the employer or a third party is responsible for defining the drug benefit. It is important to note that the data provided by the respondent are for a single plan for which the employer has chosen to respond, and are not necessarily representative of the employer's entire book of business.

The vast majority of respondents describe their pharmacy benefits as self-defined as shown in Table 2. In general, whether benefits are self-defined or not resulted in

**Table 2: Percentage of Respondents by Plan Design Responsibility**

Plan Design Decision Maker	Percentage of Employers
Employer	81%
External Organization (e.g., HMO, insurer, third-party administrator)	19%

few difference in the survey results. These differences are discussed, where believed to be relevant, in applicable sections of this report.

Respondents also were asked to identify whether they purchase PBM services as part of a coalition. The minority of employers (21%) do not buy these services as part of a coalition as illustrated in Table 3. However, this is an increase from 17% in 2002. Although this is a small change, this appears to be a trend among buyers of PBM services.

In general, whether the employer participated in a coalition or not resulted in few differences in the survey results. These differences are discussed in applicable sections of this report.

**Table 3: Percentage of Employers Participating in Coalitions**

Coalition Member Status	Percentage of Employers
Coalition Member	21%
Coalition Nonmember	79%



## RESEARCH FINDINGS

### PHARMACY REIMBURSEMENT

Discounts in retail, brand-drug AWP increased by 0.4% from 14.1% in 2002 to 14.5% in 2003. Overall, the AWP discount increased by 2.7% from 1995 to 2003. The average, retail, brand drug dispensing fee decreased from \$2.13 in 2002 to \$2.05 in 2003. The average reimbursement rate, which is a combination of average AWP and average dispensing fee, declined from 88.6% in 2002 to 87.7% in 2003. The change in reimbursement rate incorporates the changes in AWP discounts and dispensing fees in addition to changes in drug prices. These trends are shown in Table 4. See the sidebar on page 6 for a more detailed discussion regarding pharmacy reimbursement rate.

The average AWP discount for brand drugs dispensed by retail pharmacies increased by more than anticipated. This increase in discount is due in part to a change in PBM-pharmacy contracting strategies that allows the PBMs to negotiate deeper brand drug discounts in exchange for reduced generic drug discounts. Although this should theoretically lower costs for plan sponsors, PBMI is not aware of any research to confirm this.

Retail pharmacy AWP discounts also are affected by

changes in PBM calculations of copayments. Many PBMs now require patients to pay the entire copayment even when the cost of a prescription is less than the copayment. This allows the pharmacies to offer deeper discounts in exchange for recovering this lost revenue from the patient. Plan sponsors benefit from the deeper discounts and the higher cost sharing payments made by the patient.

Mail service brand drug AWP discounts also increased. The decreases in mail reimbursement are shown in Table 5. The average, brand-mail AWP discount increased by 0.7% from 19.7% in 2002 to 20.4% in 2003. Average mail dispensing fees decreased from \$0.86 in 2002 to \$0.56 in 2003. The average reimbursement rate, which is a combination of average AWP and average dispensing fee, decreased from 80.6% in 2002 to 79.7% in 2003. Because of increased competition among mail service pharmacies to increase their overall volume, mail reimbursement is expected to continue to decrease.

### Trends in Reimbursement

In 1995, 63% of employers paid retail pharmacies an AWP of 88% or greater for brand drugs. In 2003, only

Table 4: Retail Brand Reimbursement

	Average AWP	Average Dispensing Fee	Average Ingredient Cost	Average Reimbursement Rate
2003	85.5%	\$2.05	\$91.77	87.7%
2002	85.9%	\$2.13	\$79.80	88.6%
2001	86.1%	\$2.21	\$69.39	89.3%
2000	86.5%	\$2.31	\$60.34	90.3%
1999	86.9%	\$2.30	\$52.47	91.3%
1998	86.8%	\$2.35	\$45.63	91.9%
1997	87.4%	\$2.32	\$39.68	93.2%
1996	87.9%	\$2.47	\$34.50	95.1%
1995	88.2%	\$2.50	\$30.00	96.5%

Table 5: Mail Service Brand Reimbursement

	Average AWP	Average Dispensing Fee	Average Ingredient Cost	Average Reimbursement Rate
2003	79.6%	\$0.56	\$305.90	79.7%
2002	80.3%	\$0.86	\$266.00	80.6%
2001	81.1%	\$1.09	\$231.31	81.6%
2000	81.5%	\$1.15	\$201.14	82.1%
1999	82.6%	\$1.38	\$174.90	83.3%
1998	82.9%	\$1.51	\$152.09	83.9%
1997	83.4%	\$1.61	\$132.25	84.6%
1996	84.4%	\$1.71	\$115.00	85.9%
1995	85.0%	\$1.82	\$100.00	86.8%

## Calculating Pharmacy Reimbursement Rates

For purposes of measuring the impact of both aspects of pharmacy reimbursement, PBMI created a value that combines the discounted AWP and dispensing fee. This value has been labeled or referred to as "Reimbursement Rate." To create this value, PBMI converts the dispensing fee into an AWP value and adds it to the discounted AWP. These calculations are performed for both retail and mail service brand prescriptions.

In previous reports, the conversion of the dispensing fee was calculated using an assumed ingredient cost that has been held constant since 1995. This methodology evaluates changes in reimbursement in the abstract assuming no inflation. Although PBMI does not believe the average ingredient cost is the best measure of inflation, it believes calculating the reimbursement rate value using an ingredient cost number that changes over time provides more information than the previous methodology.

Because the average dispensing fee is decreasing while the average ingredient cost is increasing, the impact of the dispensing fee on the reimbursement rate also has decreased. Using an ingredient cost that increases over time causes the impact of the dispensing fee on the reimbursement rate value to decrease over time. The reimbursement rate value decreases over time regardless whether the discounted AWP or dispensing fee decreases by virtue of an ingredient cost that increases.

Tables 4 and 5 show the retail and mail information for brand prescriptions. The average reimbursement rate is calculated:

$$\text{Average Reimbursement Rate} = \text{Average AWP} + (\text{Average Dispensing Fee} / \text{Average Ingredient Cost})$$

Because the Average Dispensing Fee is decreasing while the Average Ingredient Cost is increasing, the impact of the dispensing fee on the reimbursement rate also has decreased. The Average Ingredient Cost value used is based on industry information. These calculations can be replicated using any average ingredient cost.

1% of employers reported paying an AWP of 88% or higher. Also, in 1995 none of the survey respondents reported paying an AWP less than 85%. By 2002, 11% of employers reported paying an AWP of less than 85%. See Table 6.

PBMI believes that PBM contracting strategies have changed such that plan sponsors should expect to continue to see the average retail pharmacy discounts increase slightly for the next few years.

When considering survey results based upon the various demographic data available, it appears that employers headquartered in the Northeastern region are receiving

better retail brand reimbursement rates than employers headquartered in the Western region. Northeastern region employers achieve an 87.3% reimbursement rate, whereas Western region employers achieve a 88.2% reimbursement rate as shown in Table 33 in the Appendix. Employers participating in coalitions achieved a 87.2% retail reimbursement rate while employers not participating in coalitions achieved a 87.8% reimbursement rate.

Employer size does provide some advantage. The three groups representing the largest employers achieved reimbursement rates approximately 0.5% less than that of the next three largest groups of employers. See Table 7.

Table 6: Trends in Retail Brand Discounted AWP

Percentage of Respondents	2003	2002	2001	2000	1999	1998	1997	1996	1995
< 84%	4%	2%	N/A	N/A	N/A	N/A	N/A	N/A	N/A
84%	17%	10%	7%	6%	6%	7%	3%	3%	0%
85%	32%	34%	24%	20%	15%	15%	12%	10%	10%
86%	27%	26%	26%	15%	10%	10%	6%	4%	4%
87%	19%	24%	37%	40%	40%	36%	37%	33%	23%
88%	1%	4%	6%	12%	20%	24%	26%	25%	26%
> 88%	0%	1%	1%	6%	8%	9%	17%	25%	37%



**Table 7: Retail Reimbursement by Number of Members**

Size	Average AWP	Average Fee	Reimbursement Rate
Unreported	85.7%	\$2.08	87.9%
1 - 2,000	86.2%	\$2.22	88.6%
2,001 - 4,000	85.6%	\$2.16	87.9%
4,001 - 6,000	85.7%	\$2.00	87.9%
6,001 - 10,000	85.5%	\$2.05	87.8%
10,001 - 20,000	85.1%	\$2.01	87.3%
20,001 - 50,000	85.2%	\$1.97	87.3%
50,001 +	85.1%	\$1.99	87.3%
Total	85.5%	\$2.05	87.7%

PBMI believes these differences are due in part to PBM marketing strategies involving spread pricing with retail pharmacies.

Spread pricing is the practice of PBMs retaining part of the plan sponsor payments intended for retail pharmacies. PBMs may choose to keep all of the spread amount when negotiating with smaller plan sponsors while keeping some or none of the spread when negotiating with the largest plan sponsors.

Mail service AWP discounts increased, too. In 1996, 48% of employers paid mail service pharmacies an AWP of greater than 84% for brand drugs. However, by 2003 only 3% of employers had an AWP greater than 84%. Similarly, no employers in 1996 had an AWP of 78% or less, compared with 34% of employers in 2003. These trends are reported in Table 8.

Volume, or the number of prescriptions, is an important factor in driving mail service reimbursement as shown in Table 9. Often, the number of beneficiaries is used as a proxy for claim volume. The two groups having the largest

average number of beneficiaries, achieved the lowest reimbursement rates, 79.1% and 78.7%, respectively. The three groups with the smallest number of beneficiaries, with 6,000 or less beneficiaries, achieved the highest reimbursement rates of 80.8%, 80.9%, and 80.5%, respectively.

Similarly, coalitions that combine the purchasing power of many employers receive deeper discounts. Coalition employers reported a mail-service reimbursement rate of 78.4%, while noncoalition employers achieved a reimbursement rate of 79.8%.

For those respondents that were able to provide data about claim volume, this factor appears to have a significant impact on reimbursement rates. The 20 plan sponsors reporting the greatest number of mail service claims received an average discounted AWP of 78.2%. The 20 employers reporting the least number of mail service claims reported an average discounted AWP of 80.4%.

Requiring patients to get refills through the mail service pharmacy is one way to guarantee the PBM greater volume. Respondents who require this, achieved a reimbursement rate of 79.3%, while respondents who do not require this achieved a reimbursement rate of 80.4%.

#### ADMINISTRATIVE FEES

PBM administrative fees are commonly paid on a per-claim basis. In 2001, the average administrative fee paid for each retail prescription was \$0.38. As shown in Table 10, in 2003, the average administrative fee paid for each retail prescription decreased to \$0.24. The average administrative fee paid per mail service pharmacy claim in 2003 was \$0.15, reflecting a \$0.08 decrease from 2001.

As administrative fees have become less important sources of revenue for PBMs, these fees have decreased

**Table 8: Trends in Mail Service Brand Discounted AWP**

Percentage of Respondents	2003	2002	2001	2000	1999	1998	1997	1996
< 77%	8%	4%	2%	N/A	N/A	N/A	N/A	N/A
77%	15%	7%	2%	N/A	N/A	N/A	N/A	N/A
78%	11%	15%	5%	N/A	N/A	N/A	N/A	N/A
79%	11%	12%	17%	19%	6%	5%	4%	5%
80%	23%	19%	17%	19%	17%	9%	9%	5%
81%	14%	14%	13%	13%	10%	7%	6%	4%
82%	12%	13%	20%	15%	20%	21%	15%	11%
83%	2%	7%	11%	14%	15%	19%	18%	11%
84%	2%	6%	6%	9%	14%	12%	17%	16%
> 84%	3%	3%	7%	11%	18%	27%	32%	48%

**Table 9: Mail Reimbursement by Number of Members**

Size	Average AWP	Average Fee	Reimbursement Rate
Unreported	79.7%	\$0.50	79.8%
1 - 2,000	80.6%	\$0.73	80.8%
2,001 - 4,000	80.5%	\$1.22	80.9%
4,001 - 6,000	80.3%	\$0.58	80.5%
6,001 - 10,000	79.5%	\$0.42	79.6%
10,001 - 20,000	79.4%	\$0.31	79.5%
20,001 - 50,000	78.6%	\$0.36	78.7%
50,001 +	79.0%	\$0.40	79.1%
Total	79.6%	\$0.52	79.7%

**Table 10: Average Administrative Fees Paid per Prescription**

	Retail	Mail
2003	\$0.24	\$0.15
2002	\$0.28	\$0.16
2001	\$0.38	\$0.23
1998	\$0.58	\$0.33
1995	\$0.67	\$0.34

dramatically. As the industry evolves, it will be interesting to see what role these fees play in the future.

One trend that may result in increased administrative fees is the movement toward transparency. Although the details may vary for each contract and for each PBM, transparency refers to a scenario in which the PBM collects most of its revenue from the plan sponsor's administrative fees rather than from pharmacies and pharmaceutical manufacturers. The plan sponsor will receive greater pharmacy discounts and higher rebates, but the plan sponsor will have to pay more in administrative fees.

**Table 11: Average Administrative Fees By Number of Members**

Size of Employer	Retail	Mail
Unreported	\$0.30	\$0.20
1 - 2,000	\$0.34	\$0.16
2,001 - 4,000	\$0.27	\$0.13
4,001 - 6,000	\$0.28	\$0.18
6,001 - 10,000	\$0.22	\$0.16
10,001 - 20,000	\$0.24	\$0.18
20,001 - 50,000	\$0.18	\$0.09
50,001 +	\$0.17	\$0.12
Total	\$0.24	\$0.15

In retail, large employers (50,001+ members) paid the lowest fees while smaller employers paid the highest fees (\$0.34 versus \$0.17) in retail. The administrative fees tend to follow the same rules as mail service AWP discounts, with employers with the greatest number of beneficiaries paying lower fees as shown in Table II.

Coalition members pay lower administrative fees for retail and mail claims than non-coalition members as shown in Table 12.

**Table 12: Average Administrative Fees by Coalition Member Status**

Coalition Status	Retail	Mail
Non-Coalition Member	\$0.25	\$0.15
Coalition Member	\$0.18	\$0.11

## PLAN DESIGN ISSUES

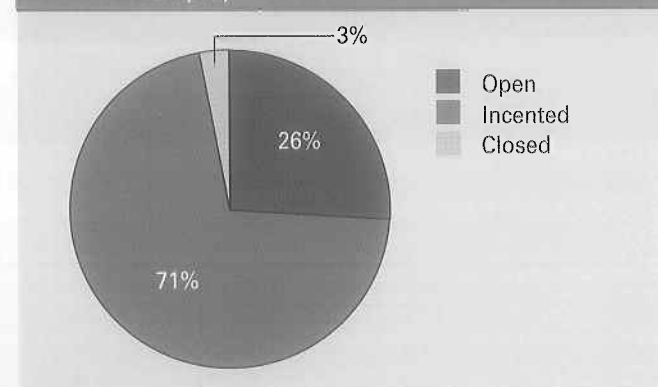
### Formulary

The use of formularies continues to increase. In 1995, only 54% of respondents reported using a formulary, however, that percentage increased to 92% in 2003. See Table 13.

For analysis purposes, formularies are grouped into three categories: closed, open, and incented formularies. The use of closed formularies makes up a very small share

**Table 13: Percentage of Employers Using a Formulary**

Year	Percentage of Employers Using Any Type of Formulary
2003	92%
2002	89%
2001	83%

**Figure 3: Type of Formulary Design Used By Employers**



of the employer-managed market. In 2003, 3% of the respondents reported using a closed formulary as shown in Figure 3. A closed formulary excludes selected drugs within a category of otherwise covered drugs. This forces patients to use the preferred drugs within the category or incur the entire cost of the prescription. The percentage of employers who offer closed formularies decreased from 8% in 1999 to 3% in 2003.

The creation of the incented (multi-tier formulary) provides plan members with a financial incentive to use the preferred drugs while preserving their access to the nonpreferred drugs. Although, the patient may not be required to pay the entire cost of a non-preferred drug, they are usually required to pay a higher copayment for non-preferred products.

One of the interesting aspects of 2003 survey results is the continued decline in the percentage of employers who report the use of an open formulary. This percentage has decreased from 67% of employers in 1999 to 26% of employers in 2003.

The traditional open formulary has been replaced by the incented formulary concept, which has grown from just 25% of employers in 1999 to 71% of employers in 2003. The migration from open to incented formularies is the culmination of several factors. As prescription drug costs increase, employers look for creative ways to increase patient cost sharing. One effective strategy is the introduction of a formulary in which a list of nonpreferred drugs is created and a higher copayment for these nonpreferred drugs is instituted.

If the formulary is designed properly, the employers can achieve lower costs through the increased use of lower cost drug products and, in some cases, higher rebates. The use of an incented formulary has been shown to increase the market share of preferred drug products. If patients choose to use nonpreferred drugs, higher copayments are collected.

The incented formulary is inescapably tied to the cost sharing scheme. Look for continued discussion about multiple tier formularies in the Cost Sharing section of this report. Future innovations in formulary management also will result in innovations in cost sharing design.

Large employers are much more likely to implement a formulary than small employers. This may be related to small employers receiving a much lower percentage of

**Table 14: Percentage of Employers Using a Formulary by Number of Members**

Size	Percent with Formulary
Unreported	75%
1 - 2,000	84%
2,001 - 4,000	88%
4,001 - 6,000	93%
6,001 - 10,000	96%
10,001 - 20,000	96%
20,001 - 50,000	97%
50,001 +	96%
Total	92%

rebates as discussed in the Rebate section of this report. See Table 14.

#### Employer Initiated Formulary Changes

Approximately 16% of the respondents indicated they had requested their PBM to make a change in some aspect of the PBM's formulary. The majority of these changes were related to the treatment of non-sedating antihistamines and proton-pump inhibitors. Based upon notes provided by the respondents, many of the changes made for these two drug classes was related to the availability of OTC versions of certain drugs (i.e., Claritin® and Prilosec®). Whether the plan sponsors chose to cover the OTC products, many chose to move the prescription drugs in these classes to nonpreferred status.

#### Rebates

Employer-PBM contracts generally dictate that formulary rebates are paid based upon one of three methods:

- Guaranteed, fixed-dollar amount per script,
- Percentage of all rebates collected, or
- Greatest amount after both calculation methods are considered.

Nearly 46% (vs. 60% in 2001) of the respondents report receiving rebates as a percentage of all rebates collected, with 46% (vs. 33% in 2001) of rebates based on a guaranteed dollar amount per prescription. Only 8% of respondents receive the greater of these two amounts. Based on three years of data and other market intelligence, it appears as though the increases in the percentage of respondents receiving a guaranteed dollar amount will continue.

THE USE OF AN  
INCENTED FORMULARY  
HAS INCREASED  
FROM 25% IN 1999  
TO 71% IN 2003



Guaranteed rebate amounts provide both parties with certainty regarding the amount to be paid. However, this method removes the potential for the plan sponsor to receive increased rebates when PBM performance improves. This method allows the PBM to benefit from the improved performance. Many plan sponsors decided that a guaranteed rebate amount outweighs the potential for higher rebate payments with improved performance and the risk of potentially lower rebate payments if performance decreases. Similarly, a guaranteed amount allows the PBM to benefit from improved performance while managing the risk of decreased performance.

As Table 15 indicates, employers receiving a percentage of the rebates receive, on average, 79% of total rebate dollars collected. Employers receiving the greater of a percentage and a fixed amount reported receiving 87% of total rebate dollars collected. As Table 16 indicates, larger employers receive a much greater percent of rebates than the smaller employers: 88% for the largest employers and 64% for the smallest.

**Table 15: Average Percentages of Rebate Dollars by Year**

Year	Percentage of Rebate Dollars
2003	79%
2002	79%
2001	73%

PBMI is unable to specify an average rebate dollar amount collected by employers who receive a guaranteed amount because of the many variables affecting this value. Some employers receive different rebate amounts for retail and mail service claims. Some employers receive rebates based upon the total number of prescriptions filled, while others receive rebates based solely on the number of prescriptions filled for preferred drugs. Some employers receive different rebate amounts for retail and mail service claims. The basis by which the data provided is calculated is often unclear from the survey responses.

Beginning in 2006, employers will have the opportunity to earn government subsidies in return for offering prescription drug benefits to Medicare-eligible employees

**Table 16: Percentage of Total Rebate Dollars by Employer Size**

Size	Percent with Formulary
Unreported	100%
1 - 2,000	64%
2,001 - 4,000	56%
4,001 - 6,000	86%
6,001 - 10,000	81%
10,001 - 20,000	76%
20,001 - 50,000	85%
50,001 +	88%
Total	79%

## Government Offers Subsidies for Retiree Drug Benefits

Employers and plan sponsors of retiree drug benefits stand to gain from recent changes to Medicare prescription drug benefits. The Medicare Prescription Drug Improvement and Modernization Act (MMA) of 2003 creates a Medicare prescription drug benefit for outpatient drugs to be called Medicare Part D. To encourage plan sponsors to continue to provide retiree drug benefits, the legislation also provides subsidies to organizations providing drug benefits to people age 65 and over.

The marketplace understanding of the MMA at this time allows for a calculation of the subsidy at a per retiree rate. MMA provides a nontaxable subsidy of 28% for allowed prescription drug costs between \$250 and \$5,000 for each retiree. This subsidy will only be paid to plan sponsors of retiree drug benefit programs who offer plans that are actuarially equivalent to a Medicare Advantage Plan or a Medicare Prescription Drug Program. The legislation provides this subsidy on the total amount paid for a retiree's drug benefit, including both the employer's and the retiree's contributions. The subsidy cap is \$1,330 per person. Administrative costs, negotiated pharmacy discounts, and rebates are excluded from the calculation.

The calculation of the subsidy is favorable to plan sponsors. For example, if a plan sponsor and retiree each pay \$500 toward the retiree's prescription drug costs, the plan sponsor will receive 28% of \$1,000 rather than just the \$500 the plan sponsor paid.

"Plan sponsors will not find it difficult to comply with the requirements to qualify for the governmental sub-

and retirees. Like rebates, these subsidies help reduce the total cost of providing drug benefits. See the sidebar beginning on page 10 regarding Medicare subsidies.

### COST SHARING

The terminology that PBMs and plan sponsors use to categorize drugs and copayments is relatively standardized.

Table 17 illustrates how most plan sponsors group drugs for reimbursement.

For purposes of this analysis, PBMI grouped drugs by tier regardless of the classification and number of tiers. Retail copayments for the first-tier increased by 4%, second-tier increased by 10%, and third-tier by 6% from 2002 to 2003. Average retail copayments are displayed in

**Table 17: Common Plan Designs for Multi-Tier Copayments**

Tier	Two-Tier Design	Three-Tier Design	Three-Tier Design	Four-Tier Design
First Tier	Generic	Generic	Generic	Generic
Second Tier	Brand	Single Source Brand	Preferred Brand	Preferred Brand
Third Tier	NA	Multiple Source Brand	Non-Preferred Brand	Non-Preferred Brand
Fourth Tier	NA	NA	NA	Biotech drugs, lifestyle, nonformulary, or other high cost drugs

NA= not applicable.

**Table 18: Average Retail Copayment Amounts for All Respondents**

Survey Year	Average Copayment Amount		
	First Tier	Second Tier	Third Tier
2003	\$8.66	\$19.26	\$35.15
2002	\$8.33	\$17.57	\$33.23
2001	\$7.68	\$16.06	\$30.51
2000	\$7.17	\$14.14	\$27.35
1999	\$7.05	\$12.82	\$23.40

**Table 19: Average Mail Service Copayment Amounts for All Respondents**

Survey Year	Average Copayment Amount		
	First Tier	Second Tier	Third Tier
2003	\$16.63	\$37.33	\$67.55
2002	\$14.61	\$31.21	\$60.61
2001	\$12.60	\$26.01	\$55.23
2000	\$10.78	\$21.29	\$45.73
1999	\$9.74	\$17.96	\$37.67

sidy," said Edward Kaplan, senior vice president and national health practice leader for the Segal Company. Kaplan's consulting practice focuses on health care and drug benefit plan design for employers, governments, and collectively bargained plans.

"The first step is to determine if your plan design is actuarially equivalent to the new drug benefit Medicare will offer," Kaplan said. "If organizations start analyzing their benefit offerings now, there is time to make the necessary plan design changes to qualify for the subsidies that begin in 2006."

Plan sponsors requesting the subsidy also must agree to comply with an audit. The final reimbursement mechanism and auditing methodology will be established by the U.S. Department of Health and Human Services.

"It is clear the Medicare Modernization Act will create massive change in the landscape and financing of retiree health care," Kaplan asserted. "Plan sponsors can redefine their retiree health plans to take advantage of the federal subsidies and eliminate substantial amounts of future retiree health claim expenses without abandoning workers."

### On-line Resources

Centers for Medicare and Medicaid Services: <http://cms.hhs.gov>

Overview of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 produced by the Library of Congress' Congressional Research Service: <http://gordon.house.gov/NR/rdonlyres/68AF7486-66FF-4518-9FCA-C7E5A24E7956/0/medicareprescripdrubexplanation.pdf>

Supplemental information on MMA Part D and retiree health benefits: <http://www.kff.org/medicare/index.cfm>

Table 18. These increases are more pronounced in mail as shown in Table 19. From 2002 to 2003, average first-tier mail service copayments increased by 14%, second-tier increased by 20%, and third-tier by 11%.

To provide some perspective about the scope of change over the past four years, PBMI reports the distribution of second-tier copayments for both retail (Table 20) and mail (Table 21) for the past four years. The use of retail second-tier copayments of more than \$20 increased from 4% in 2000 to 31% in 2003. For mail service, the

percentage of copayments of \$40 or more is now 52%.

Employers understand that cost sharing is a valuable tool to encourage patients to behave in certain ways. For example, one of the purposes of having multiple copayment tiers is to encourage generic drug use. Today, the retail third-tier copayment (where most plans categorize multi-source brand drugs) is more than four times the first-tier copayment versus three times the first tier copayment in 1998. This is a significant incentive to use generic drugs which are commonly placed in the first tier.

Table 20: Distribution of Employer Retail Second-Tier Copayments by Dollar Amount

Copayment by Dollar Amount	2003	2002	2001	2000
< \$10	5%	7%	10%	13%
\$10-\$11	7%	11%	12%	22%
\$12-\$13	2%	4%	8%	8%
\$14-\$15	21%	24%	27%	28%
\$16-\$20	34%	38%	34%	25%
> \$20	31%	17%	10%	4%

Table 21: Distribution of Mail Service Second-Tier Copayments by Dollar Amount

Copayment by Dollar Amount	2003	2002	2001	2000
<\$15	4%	11%	18%	28%
\$15-\$19	6%	7%	10%	15%
\$20-\$24	8%	15%	18%	21%
\$25-\$29	8%	7%	9%	7%
\$30-\$34	17%	18%	19%	16%
\$35-\$39	3%	3%	27%	14%
\$40-\$44	24%	24%	Not calculated	Not calculated
> \$44	28%	15%	Not calculated	Not calculated

Consumer-directed plan designs also create new ways to incent members to purchase prescription drugs and health care services more cost effectively as discussed in the sidebar.

In the past, mail service copayments were kept low relative to retail copayments to encourage mail service use. The belief was that mail service was a lower cost distribution point for prescriptions. However, employers have learned that mail service will not produce savings for the employer unless copayments are structured appropriately. Many employers discovered that setting mail copayments too low compared to retail copayments resulted in mail service prescriptions costing more to the employers after the cost-sharing amount is collected than did retail pre-

scriptions.

In an attempt to correct this problem, plan sponsors have increased mail service copayments more quickly than retail copayments for the last few years. The mail service second-tier copayment is now 1.9 times the retail second-tier copayment. This is as compared to 1.6 times in 2001.

For more information on the economic benefits associated with mail service pharmacy, see sidebar on mandatory mail service plan designs.

### Three-Tier Copayments

The use of a three-tier plan design, in which the tiers are based on formulary status, continues to gain favor among employers. In 1998, only 6% of employers report-



## Market Slow to Embrace Consumer-Directed Products

Consumer-directed or consumer-driven health plan designs are intended to encourage patients to make more deliberate decisions about how they spend health care benefit dollars. Rather than simply accepting decisions made by their employers' health care providers, patients are given a financial incentive to look for less costly, but still medically appropriate, services.

Although the market for these products is somewhat immature, there are some relatively common benefit design characteristics. These characteristics include high deductibles and percentage coinsurance. Because patients are affected financially when they consume more resources, open access also is a common characteristic. The plan designs are supported by a Health Reimbursement Arrangements (HRA) or a Health Savings Account (HSA). HRAs are employer-funded mechanisms for employee-controlled reimbursement of medical costs. HSAs can be funded by employer, employee, or both. The U.S. Treasury and the Internal Revenue Service have guidelines for the establishment and contribution of both the HRAs and HSAs. Visit [www.ustreas.gov](http://www.ustreas.gov) for detailed information.

Several plan sponsors have implemented this type of program as strictly a drug benefit. However, according to one benefit administrator, plans are moving toward integrating the drug benefit with medical benefits. In addition to streamlining administration, this approach is believed to create incentives for consumers to limit expenditures on prescription drugs. Because the integrated deductibles are high, many, if not most, patients will end up paying all the prescription drug expenditures because they never reach the deductible.

Ignoring for the moment whether drug benefit costs are paid by the patient prior to the deductible being reached or through an HRA or HSA, when the drug benefit incorporates a consumer-driven design, many anticipate total drug benefit costs to decrease. Because consumer-driven health plans are relatively new, data from the utilization data available is relatively limited. However, based upon information presented jointly by Blue Cross Blue Shield of Minnesota (BCBSMN) and Prime Therapeutics during PBMI's annual conference, it is reasonable to expect some decrease. Depending on the new drug benefit design implemented with the consumer-directed incentive, three areas in particular generate savings: cost sharing, generic dispensing, and mail service use. After individuals met their annual deductibles, prescription claims were reimbursed based on the copayment structure detailed in the table below.

BCBSMN and Prime Therapeutics found this plan design increased year-to-date generic dispensing rates and mail-order pharmacy utilization. Preliminary data show the average plan total cost per net claim decreased as well. These organizations continue to study the utilization and cost trends to better

understand the impact of consumer-directed plan design variables on total benefit costs.

PBMI's 2004 survey included a question about consumer-driven health plans. A very small number of employers indicated that some portion of their beneficiaries were enrolled in a consumer-driven health plan. However, follow-up discussions determined this was incorrect. This flawed survey data may result from organizations having vastly different definitions for consumer-directed plan designs. PBMI will continue to watch adoption of consumer-directed products and incorporate more questions about this benefit design option when it becomes more prevalent.

Prescription Copayments After Meeting Deductible

Copayment Tier	Retail Pharmacy (34-day supply)	Mail-order Pharmacy (90 day supply)
Generic	\$10	\$20
Preferred Brand Name	\$25	\$45
Nonpreferred Brand Name	\$40	\$70
Lifestyle	Full Cost at Discounted Rate	N/A

ed the use of this three-tier plan design. This number has increased from 46% in 2001 to 72% in 2003. Likewise, the percentage of employers who offer two-tier cost sharing schemes declined from 47% in 2001 to 24% in 2003. It is expected that the industry will continue to see growth in the percentage of employers offering three-tier or more than three-tier plan designs. The use of a three-tier plan based on the type of drug (e.g., generic, single-source brands, and multi-source brands) decreased to 4% after remaining constant at 7% for three years. These percentages are based on respondents who use copayments, excluding those who use coinsurance percentages.

#### Four-Tier Copayments and More

PBMs and managed care organizations periodically announce or propose new cost sharing schemes that they believe will help plan sponsors better control costs. Plan sponsors have been relatively slow to adopt these new schemes. This year, 13 respondents reported using a fourth tier to improve cost sharing. This copayment amount is in many instances equal to the entire cost of the drug. Typically, this category is used for lifestyle drugs; in other cases it represents nonformulary drugs.

One concept that may have a significant impact on cost sharing, if adopted, is reference pricing. For reference pricing, the plan sponsor or PBM would establish the

## Well-Structured Mandatory Mail Provision Saves Money

Although there are factors that can reduce the cost advantage of mail service pharmacies as compared to retail pharmacies, most people agree that mail service pharmacies have the potential to decrease prescription drug benefit costs. Average Wholesale Price (AWP) discounts and rebates tend to be greater from mail service with very low or non-existent dispensing fees. The difference between the average reimbursement rate (see Pharmacy Reimbursement section for a definition and reimbursement rate data) for retail and mail service brand drugs is approximately 12% of the AWP of the ingredient cost.

As determined by PBMI's analysis of 2004 survey utilization data, requiring mail service use greatly increases mail service use. On average, plans that do not require mail service use achieve 14% utilization rates as opposed to 27% for plans with mandatory mail service. In return for a mandatory mail service benefit design, plans received slightly deeper discounts; approximately 1% of AWP on average.

As part of this survey, PBMI interviewed some of the respondents that had implemented a mandatory mail service requirement to learn more about effective implementation and results.

### Implementation

Plan sponsors dictate when the requirement to have a prescription dispensed by the mail service instead of the retail pharmacy is triggered. The requirement is typically activated after the first, second, or third prescription refill is filled at retail. After the retail limit has been reached, future refills at retail pharmacies are denied and refills can only be obtained through a mail service pharmacy.

Other than specifying the number of refills allowed at retail, the only other decision a plan sponsor normally makes is establishing the copayment or coinsurance levels. Plan sponsors commonly provide beneficiaries an incentive or reward in conjunction with the requirement to use mail. This incentive is usually in the form of reduced cost sharing. For example, requiring the patient to pay the equivalent of two retail (30-day prescription) copayments for a 90-day mail service prescription. This results in the savings of one copayment for the patient.

Whether mail service results in savings for the plan sponsor depends largely upon the difference in retail and mail service pharmacy reimbursement rates and how cost sharing is structured. In essence, the savings provided through mail service versus retail must exceed the copayment incentive given to the beneficiaries. With increases in both copayment amounts and drug costs, it is becoming harder to offer an incentive to patients and still achieve savings through mail order.

amount the plan would pay for each prescription for a group of drugs rather than establishing the amount the patient pays. In this case, the patient pays the difference. The plan sponsors' amount is fixed, the patient's payment varies based upon the price of the drug. This gives patients an incentive to use the lowest cost drug that is appropriate for their needs.

### Coinsurance

The percentage of employers using coinsurance for second-tier retail cost sharing increased from 22% in 2001 to 26% in 2002 to 30% in 2003. Although most employers who use coinsurance generally use coinsurance

for all drug categories, some employers use coinsurance only for second- or third-tier drug prescriptions, but not for first-tier drug prescriptions. This approach for the second- and third-tiers allows plans more flexibility to ensure patients pay a consistent portion of the benefit cost, while providing an additional incentive to use generic drugs.

Coinsurance often is used in combination with a minimum and or maximum copayment amount. Some respondents use one, while others use both the minimum and maximum. The average second-tier, minimum copayment for coinsurance plans is less than the average copayment for respondents with copayment plans (\$15.43 vs.

### Calculating Retail and Mail Differentials

It is very simple to perform the calculations to determine whether savings can be achieved with various levels of pharmacy reimbursement and cost sharing. For example, assuming a 90 day prescription with an undiscounted ingredient cost of \$225 and average discounts and copayments from 2004 survey findings.

In this example, mail service is not less expensive than retail for the plan sponsor. The plan sponsor pays \$1.55 more for the prescription dispensed through mail service given the assumptions used. However, the patient saves \$20.45. If the goal of the plan sponsor is to save money by using mail service, too much of an incentive has been given to the patient. When calculating actual differences between retail and mail prescription costs, plan sponsors must take into accounts all cost factors in making these calculations. Rebates and administrative fees have not been included in this example.

The lesson from this is some incentive needs to be offered, but some control needs to be maintained. "Initially members saved one month of copay on a 90-day mail service prescription. Now, to maintain some balance, they only receive one-half month of copay discount. If we ever reached the point members received no savings, we'd have to make mail service optional," said one benefits manager.

With the introduction of mandatory mail service requirement comes a need for increased communication. According to one human resources professional, "It took a while for employees to get used to it. People didn't pay attention to the communication, so they got caught on their third refill. They had to go to mail and didn't realize it."

Employees have a number of other questions. Reports one plan sponsor. "We took all the questions asked and developed a page and a half question and answer format document that we hand out to everyone. How does this work and what if this happens to me type questions."

#### Retail and Mail Differentials

Element	Value
Undiscounted Ingredient Cost	\$225
Mail Service Pharmacy Discounted AWP	79.6%
Mail Service Pharmacy Dispensing Fee	\$0.52
Mail Service Pharmacy Prescription Cost	\$179.62
Patient Cost Share	\$37.33
Plan Sponsor Cost	\$142.29
Retail Pharmacy Discounted AWP	85.5%
Retail Pharmacy Dispensing Fee (\$2.05 per 30 Days)	\$6.15
Retail Pharmacy Prescription Cost	\$198.53
Patient Cost Share (\$19.26 per 30 Days)	\$57.78
Plan Sponsor Cost	\$140.74
Net Patient Savings	\$20.45
Net Plan Sponsor Savings	(\$1.55)



\$19.26). Although used less frequently, the average maximum copayment (\$40.70) is more than two times the average minimum copayment for coinsurance plans.

On average, beneficiaries pay about 20% of the cost of their retail prescription for drugs in the first tier, 26% for drugs in the second tier, and 40% for drugs in the third tier as shown in Figure 4. The use of the three-tier copayment structure has encouraged employers to differentiate the coinsurance percentage among the three categories. Using a higher percentage coinsurance for the third tier increases the incentive to use lower cost drugs in the first tier.

Coinsurance is used much less frequently for mail service. Only 17% of the respondents (an increase from 12% in 2002) have a coinsurance component for second-tier mail service prescriptions. Although the barriers related to using coinsurance in mail service have been eliminated at most mail service pharmacies, many employers are still reluctant to implement this feature for mail service. See Figure 5 for more information about the coinsurance percentages reported.

For retail prescriptions, the Southern region tends to have higher copayments than the other regions while the Midwestern region uses coinsurance more frequently than the other regions (see Table 22). For retail prescriptions, large employers tend to be more frequent users of coinsurance (see Table 23). For mail service prescriptions, the largest employers have higher copayments than the other employer groups and tend to use coinsurance more frequently (see Table 24).

Employers who define their own benefit plans are more likely to use coinsurance. Twenty-four percent of respondents who defined their own plans use coinsurance as opposed to 13% of the respondents whose plans are defined by other parties. PBMI suspects that many of the respondents who use a third-party to define their benefit plan are using managed care organizations (MCOs). Traditionally, MCOs are not frequent users of coinsurance.

Figure 4: Average Retail Coinsurance Percentages for Each Tier

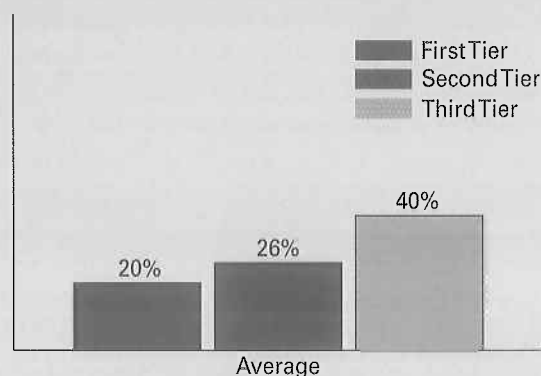


Figure 5: Average Mail Service Coinsurance Percentages for Each Tier

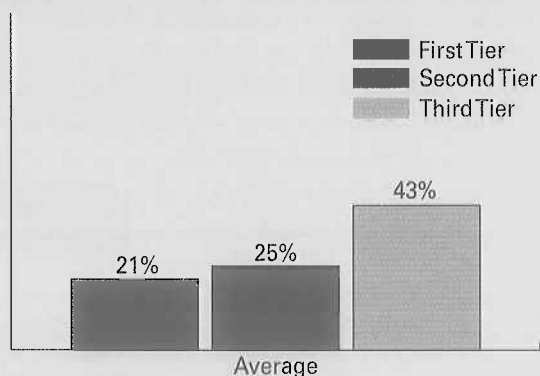


Table 22: Retail Cost Sharing by Geographic Region

Region	Average Copayments			Percent With Coinsurance
	First Tier	Second Tier	Third Tier	
Unknown	\$9.16	\$18.95	\$35.29	5%
Northeast	\$8.19	\$18.26	\$34.14	29%
South	\$9.73	\$21.70	\$37.14	20%
Midwest	\$8.11	\$17.94	\$33.94	40%
West	\$7.88	\$18.75	\$34.64	33%
All	\$8.66	\$19.26	\$35.15	30%

Table 23: Retail Cost Sharing by Number of Members

Region	Average Copayments			Percent With Coinsurance
	First Tier	Second Tier	Third Tier	
Unreported	\$5.42	\$12.08	\$32.50	25%
1 - 2,000	\$8.88	\$19.55	\$34.44	22%
2,001 - 4,000	\$9.13	\$19.97	\$34.83	17%
4,001 - 6,000	\$8.32	\$20.33	\$37.52	27%
6,001 - 10,000	\$8.64	\$19.68	\$34.06	25%
10,001 - 20,000	\$9.37	\$20.59	\$37.81	37%
20,001 - 50,000	\$7.79	\$16.57	\$31.19	38%
50,001 +	\$8.59	\$18.76	\$35.90	41%
Total	\$8.66	\$19.26	\$35.15	30%

Table 24: Mail Service Cost Sharing by Number of Members

Region	Average Copayments			Percent With Coinsurance
	First Tier	Second Tier	Third Tier	
Unreported	\$11.67	\$25.00	\$32.50	0%
1 - 2,000	\$16.83	\$37.15	\$66.43	15%
2,001 - 4,000	\$16.91	\$37.56	\$62.26	8%
4,001 - 6,000	\$17.32	\$38.97	\$71.40	14%
6,001 - 10,000	\$16.91	\$40.15	\$68.03	9%
10,001 - 20,000	\$16.17	\$37.02	\$68.52	16%
20,001 - 50,000	\$15.25	\$31.68	\$61.30	25%
50,001 +	\$17.58	\$40.39	\$76.48	29%
Total	\$16.63	\$37.33	\$67.55	17%

## DRUG COVERAGE

For the past several years, PBMI surveyed plan sponsors about their coverage decisions for many different drugs. The survey simply asked whether these drugs were covered. We noted little change in the answers over the past few years. Plan sponsors decided whether to cover these drugs and, for the most part, nothing was causing them to change their decisions.

Although plan sponsors are not changing the drugs that they cover, they are changing how they cover those drugs. There are several issues that impact specific drug coverage decisions. One, some new drugs being introduced are not viewed as being significantly better than their predecessors. Rather than automatically paying for these drugs, plan sponsors want their beneficiaries to try the less expensive, predecessor drugs first. Two, some of the drugs have become available OTC. Traditionally, plan sponsors do not cover OTC products. Plan sponsors are deciding whether they will cover the OTC product. They also are deciding whether they will cover prescription

drugs that have therapeutically equivalent OTC alternatives. Third, the introduction of additional cost sharing tiers, e.g. the third and fourth tiers, provide plan sponsors with options. Rather than excluding certain drugs, the drugs can be moved to higher tiers providing patients with an incentive to use the preferred products. See the following sidebar on creative ways to benefit from the savings associated with OTC drugs.

PBMI surveyed plan sponsors about three groups of drugs; nonsedating antihistamines, proton pump inhibitors, and Cox-II inhibitors. These categories are some of the highest cost categories for many plan sponsors and are the focal point of many management activities. The survey results for these drugs are identified below.

### Nonsedating Antihistamines

Nonsedating antihistamines provide allergy relief without the sedating effect of predecessor drugs such as Benadryl®. In 2003, Claritin® became available as an OTC product and all prescription versions of the product



## Plan Sponsors, Health Plans Rethink OTC Coverage

There are more than 80 therapeutic categories of over-the-counter (OTC) drugs marketed in the United States, according to the U.S. Food and Drug Administration's Center for Drug Evaluation and Research. An OTC drug does not require the advice of a health practitioner for safe, effective use and typically has:

- Benefits that outweigh risks of therapy,
- Low potential for misuse and abuse,
- Capability to be used by consumers for self-diagnosed conditions, and
- Adequate labeling.

U.S. consumers are accustomed to using OTC cough, cold, and pain medications to treat relatively minor maladies. Historically, if no prescription was required to buy an OTC product, the presumption was that the drug had less clinical value than a prescription drug. This has changed as more than 700 OTC products now contain ingredients that were once available only by purchasing prescription drugs less than 30 years ago, according to data released by the Consumer Healthcare Products Association (CHPA) in 2001. OTC drugs save U.S. consumers about \$20 billion a year in health care costs, inclusive of prescription costs, doctor visits, lost time from work, insurance costs and travel, etc. based on a research study by Kline and Company in 1997.

The number of OTC products containing previously prescription drug ingredients has increased as pharmaceutical manufacturers have looked for opportunities to extend the life of their brand-name products. When brand drugs lose their patent protection, their market share is quickly captured by lower cost generic drugs. The revenue generated by the brand drug drops quickly and dramatically. The conversion of brand drugs to OTC status allows manufacturers' revenue streams to continue. Manufacturers are now exploring opportunities to convert a number of new drugs to OTC status such as Cox-2 inhibitors, cholesterol medications, migraine treatments, and anti-obesity drugs.

### Antihistamines Get Things Started

One of the OTC categories first pursued for coverage was OTC antihistamines such as Benedryl®. In this instance, patients were encouraged to use the OTC product at night rather than the more costly prescription non-sedating antihistamines (NSAs) such as Claritin® or Allegra®. The next group of drugs that sparked interest from plan sponsors was the H2 Antagonist category; Axid®, Pepcid®, Tagamet®, and Zantac®. These drugs are used in the treatment acid reflux and ulcers were precursors to proton pump inhibitors (PPIs). Tagamet® was the first H2 to be made available OTC in 1995 at a lower strength than its legend drug counterpart; though all of the other H2 blockers soon became available without a prescription).

Very few plan sponsors implemented coverage of OTC antihistamines and H2 antagonists. This was, in part, due to the introduction of prescription products with perceived therapeutic advantages with the evolution of nonsedating antihistamines NSAs and PPIs.

### Newer OTCs Eclipse Prescription Drugs

Recent product introductions that have finally resulted in more plan sponsors adopting an OTC coverage strategy are in the NSA and PPI categories. Claritin®, the highest cost NSA at one time for most plan sponsors, is now only available OTC. Prior to the availability of OTC Claritin®, this class was one of the highest cost categories for many commercially insured plan sponsors. Prilosec®, the highest cost PPI for many plan sponsors, is now available in both 10 mg OTC and higher dosage prescription forms.

One of the reasons PBMI believes plan sponsors appear to be reacting more aggressively with these two products is that the next generation prescription drugs that followed Claritin® and Prilosec® to the marketplace have been reported by many clinical sources as not offering significant clinical improvements over the prior generation

products. Plan sponsors are weighing in with their opinions of these drugs by modifying their PBMs' classification of these drugs in formulary and cost sharing categories.

OTC products tend to be much less expensive than prescription drugs. As a result, plan sponsors are trying several ways to leverage the savings associated with OTC products that are therapeutically equivalent to prescription drugs.

#### **Plan Coverage of OTCs**

The plan sponsors that initially explored OTC coverage tended to be managed care organizations with group model HMOs that dispensed prescriptions from their own pharmacies. The self-owned pharmacies provided health plan members with access to OTC products while providing pharmacist oversight and management of who received them as a covered benefit.

"Many health plans that cover OTC products place them in the first or second tier copayment category," says Shobhna Butler, PharmD, president and chief executive officer of B. Wellness Consulting, Inc. These organizations follow the insulin model, requiring that members present a prescription at the pharmacy for processing, Butler reports.

#### **Strategies for Employers**

"Although it's not yet prevalent for employers to provide coverage for all OTC drugs, some employers are picking up the tab for select OTC products," says Tim Watson, PharmD, MBA, founder and president of Pharmaceutical Strategies Group.

"We are going to see employers encourage employees to use their Health Savings Accounts (HSAs) and Medical Savings Accounts (MSA) since the U.S. Treasury Department issued its ruling in the fall of 2004 that allows use of these funding mechanisms for purchasing OTC products to treat existing medical conditions," Watson says.

"The IRS ruling came out too late for many employers to use this strategy for 2004," he reports, because many employers had to review the overall terms of the HSAs offered by their plan. "Encouraging the use of flexible spending accounts can benefit both employer and employee. Employees benefit because contributions can be made to these employer sponsored programs on a pre-tax basis. Employers benefit by reducing the amount they pay for prescription products that have OTC alternatives. Employers can encourage the utilization of the OTC product by a variety of means, including offering coupons, eliminating copays for a period of time, placing therapeutic alternatives to the OTC product in the highest formulary tier. When estimating the costs and benefits of a comprehensive OTC coverage strategy, employers should consider the cost of any incentives offered, costs to communicate the program, and incremental costs that may be charged by the HSA administrator," says Watson. "Employers are rapidly adopting this approach to OTC drugs for 2005."

#### **Barriers to OTC Coverage**

There are a number of issues plan sponsors must resolve when deciding whether and how to cover OTC products. These issues focus on concerns related to self-diagnosis. The concerns many have is that their beneficiaries may buy and consume OTC products they do not have a medical need for, that they may not seek treatment from a medical professional in a timely manner, and, as a result, harm may inadvertently fall upon their beneficiaries.

However, the desire to encourage the use of appropriate OTC products does not necessarily translate into an attempt to reduce or eliminate the prescriber's role in healthcare delivery. Although a prescription is not required to buy an OTC product, plan sponsors may still wish to require a prescription for an OTC product to be a covered drug under an employer-sponsored prescription benefit plan.

"Employers can work with their PBMs to have network pharmacies adjudicate prescriptions for OTC products," says Watson. He explained the PBMs load the 11-digit National Drug Code (NDC) numbers for the OTC

products into their systems and process the claim with the same clinical and system edits used for legend prescription drugs.

Requiring a prescription provides the plan sponsor with the assurance that the patient is receiving the advice of a licensed prescriber. Although some could argue that this is unnecessary for some OTC categories such as NSAs, there may be categories of drugs that become available OTC in the future for which this control is desired. Calcium channel blockers, commonly used to treat high blood pressure, are a likely a candidate for OTC conversion. Hypertension and other asymptomatic diseases are more difficult for patients to self-diagnose as well as self-monitor. Another benefit of requiring a prescription to be adjudicated at the point of sale is that traditional PBM edits for drug-drug interactions can be included.

A prescription also provides some administrative control over OTC coverage. The prescription will give some assurance that the use and cost experienced will be for covered individuals with a legitimate medical need. Educating consumers about the availability of OTCs and the drugs they replace, as well as the impact on out-of-pocket costs will reduce many of the barriers to expansion of OTC coverage.

### Benefits of OTC Coverage

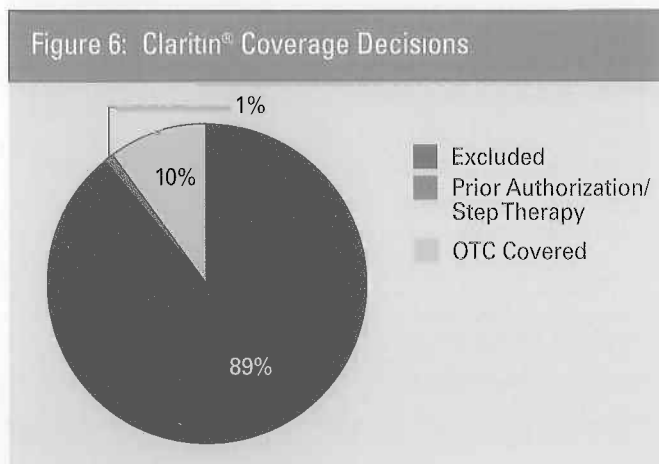
The obvious benefit of covering OTC products is the reduced cost to plan sponsors by substituting lower cost OTCs for higher cost prescription drugs. The savings comes from the "Rx-to-OTC switch". For example, WellPoint Pharmacy Management reported reducing the use of prescription NSAs by 50% from January to April 2003, compared to the same six-month period in 2002 when all NSAs were still legend drugs. It should be noted that additional savings in the form of reduced medical costs may accrue if a prescription is not required for OTC products.

In addition to economic benefits, there are intangible benefits for OTC coverage. "Expanding coverage of OTC drugs involves consumers more in their own health care," says Watson. "This is beneficial for plan sponsors in all segments of the market because of the savings and having more knowledgeable employees."

### On-line Resources

- Consumer Healthcare Products Association: [www.chpa-info.org](http://www.chpa-info.org)
- U.S. Food and Drug Administration: <http://www.fda.gov/cder/offices/otc/default.htm>

were removed from the market. Figure 6 shows the coverage status of Claritin® by percentage of plan sponsors. In a departure from past behavior, 10% of plan sponsors



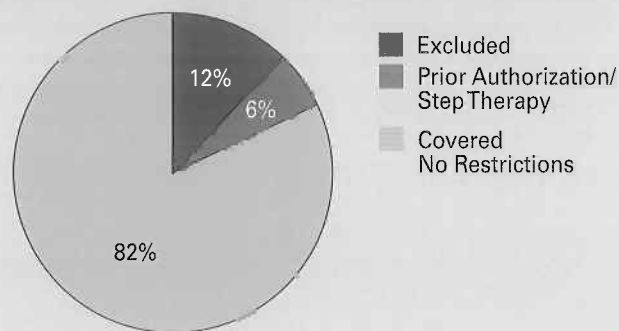
cover this OTC formulation of Claritin®.

The availability of a nonsedating antihistamine in an OTC form is important because it provides plan sponsors with coverage options for the other nonsedating antihistamines. Regardless whether a plan chooses to cover the OTC product, the plan may choose, among other options, to exclude all other prescription nonsedating antihistamines. (See Figure 7). Twelve percent of plan sponsors have chosen to exclude the other nonsedating antihistamines.

For plans with three-tier copayment schemes, most plan sponsors have one or more of these drugs in both the second and third tiers. Some (30%) plan sponsors have moved all these drugs to the third tier. The cost of the OTC product is less the third-tier copayment for most plans. Many patients may opt to use the OTC product



Figure 7: Other Non-Sedating Antihistamine Coverage Decisions

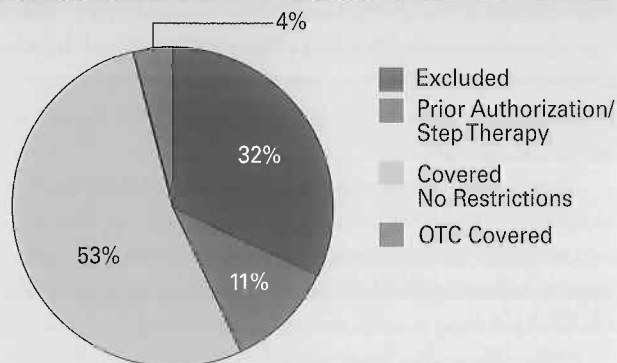


rather than pay the third-tier copayment. Other patients may choose not to use either when faced with the higher copayment or paying for the OTC product.

### Proton-Pump Inhibitors

Proton-pump inhibitors are used to treat ulcer symptoms. The introduction of OTC Prilosec® and its generic, omeprazole, are causing changes in this drug class. Because the OTC formulation of Prilosec® is indicated for 14 days of treatment, only 32% exclude the prescription formulation from coverage. A mere 4% of plan sponsors cover the OTC version of Prilosec®. This difference is because that Prilosec® is still available as a prescription drug. Claritin® is not. Only 4% of plan sponsors cover the OTC version of Prilosec® while 10% cover OTC Claritin®. This difference may also be due to the fact that Prilosec® is available generically. (See Figure

Figure 8: Prilosec® Coverage Decisions



8).

In addition to the introduction of OTC and generic Prilosec®, came the introduction of a next generation PPI; Nexium®. In part, because of published concerns that this new product is only slightly more effective than the previous generation of products, 9% of the plan sponsors have chosen to exclude Nexium®. (See Figure 9). In addition, 16% require prior authorization or step therapy before it can be used, indicating a desire to encourage patients to use the older, less expensive products first.

There are several other PPIs available. Plan sponsors treat them similarly to Nexium®. The primary difference being only 4% excluded these drugs versus 9% for Nexium®. (See Figure 10).

For plans with three-tier copayment schemes, approximately 60% place Prilosec® in the third tier and 60%

THREE-TIER  
COPAYMENT STRUCTURES  
GIVE PATIENTS A  
FINANCIAL INCENTIVE  
TO USE OLDER, LESS  
EXPENSIVE THERAPIES.

Figure 9: Nexium® Coverage Decisions

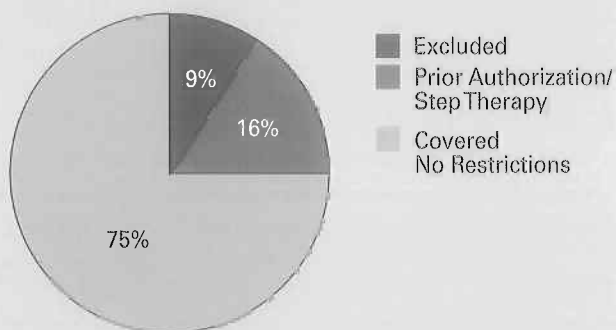
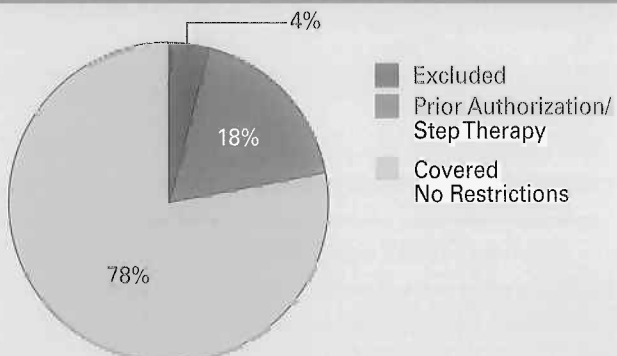


Figure 10: Other PPI Coverage Decisions



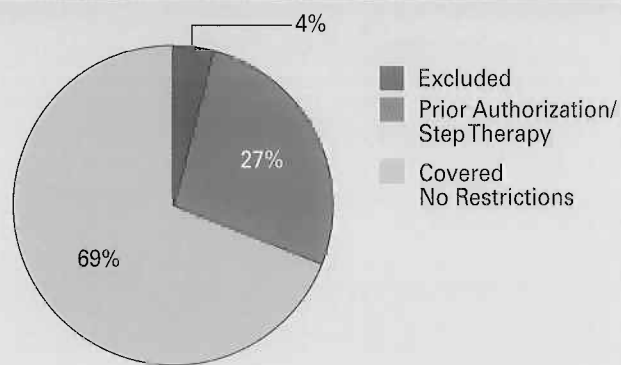
place Nexium® in the third tier. Plans tend to treat both Prilosec® and Nexium® in the same manner with both either placed in third-tier or both in second-tier. This is most likely because of the formulary design of the PBMs administering the plan sponsors' benefits.

### Cox-II Inhibitors

Cox-II Inhibitors such as Celebrex®, and Bextra® are marketed as being better at pain control than older non-steroidal anti-inflammatory drugs (NSAIDs) and better at reducing the potential for ulcers often associated with NSAID use.

Although studies have questioned the cost-effectiveness of the Cox II drugs versus NSAIDs, only 4% of the respondents exclude the Cox II drugs. See (Figure 11). A better reflection of this concern is that 27% of the respondents require some prior authorization or step therapy before the costly drugs are covered. This means patients must try the older therapies first before the Cox-II drugs are covered.

Figure 11 Cox II Coverage Decisions



This concern is also reflected in the copayment tier placement of these drugs. More than 27% of the respondents report that all the Cox-II drugs are in the third tier. The patients have a financial incentive to use the older, less expensive therapies.

## UTILIZATION PATTERNS

PBMI collects a limited amount of utilization data to quantify the impact of various benefit plan design elements on utilization. Survey respondents reported a 14% increase in costs from 2002 to 2003. The change in costs cannot be compared with changes reported in previous years because the basis for the cost changed from after cost share dollars in 2002 to before cost share dollars in 2003. The trend rates reported range from an increase of 65% to a decrease of 7%.

### Mail Service Utilization

Employers experience a broad range of total prescriptions that are dispensed through the mail service pharmacy as illustrated in Table 25.

**Table 25. Range of Mail Service Utilization**

Point in Range	Percentage of Total Prescriptions Dispensed by Mail Service Pharmacy
Lowest Use Percentage	0%
Average Use Percentage	16%
Highest Use Percentage	66%

Mail service use can be encouraged through the use of cost sharing incentives or by requiring refills for maintenance drugs to be dispensed through the mail service pharmacy.

Table 26 illustrates the impact of mandatory mail service use on refilling maintenance prescriptions. Mail service utilization almost doubles when mail service is required for maintenance prescriptions.

**Table 26: Impact of Mandatory Mail Service on Mail Service Utilization**

Mail Service Status	Percentage of Total Prescriptions Dispensed by Mail Service Pharmacy
Voluntary Mail	14%
Mandatory Mail	27%

The data on the impact of cost sharing on mail service use is not as clear because mail service utilization is, in part, dependent upon population demographics such as age and gender. PBMI does not currently capture these data in its survey.

### Generic Utilization

One of the most effective strategies to reduce drug benefit costs is to increase generic drug utilization. Generic drugs, as defined by the U.S. Food and Drug Administration (FDA), are the chemical equivalents of their brand-name counterparts and therefore identical in terms of safety and effectiveness. Generic drugs are much less expensive than brand-name products. Initially, because of concerns about safety and efficacy, patients and some physicians were slow to accept a generic drug in lieu of the brand-name drug. As costs sharing incentives and generic drug options have increased and patients have become more familiar with the use of generic drugs, patients are more willing to accept the generic product instead of the brand-name alternative.

Average retail generic utilization increased from 41.5% in 2002 to 44.1% in 2003. Average mail service generic utilization increased from 31.8% in 2002 to 34.0% in 2003. These rates are expected to continue to increase as more drugs become available generically, cost sharing incentives increase, and more and different utilization management programs are implemented.

As shown in Table 27, there is a broad range of generic dispensing rates for both mail service and retail. For those employers with the highest rates of generic utilization, there may be unique features that allow them to reach these levels of generic dispensing. Mail service generally has lower generic dispensing rates because the drugs most commonly dispensed through mail are not available generically.

**Table 27: Range of Generic Dispensing Rate in Retail and Mail Service Pharmacies**

Point in Range	Percentage of Retail Pharmacy Prescriptions	Percentage of Mail Service Pharmacy Prescriptions
Lowest Percent Generic	8%	12%
Average Percent Generic	44%	34%
Highest Percent Generic	67%	60%

Employers can encourage generic utilization in several ways. This includes cost sharing design, generic detailing and education of prescriber network, and plan member education among others. Although PBMI examines generic utilization by some of these factors individually, it is their combined impact that determines the outcome.



For example, simply setting the generic copayment lower than the brand-name drug copayment can encourage generic drug utilization. However, if the difference between the brand and generic copayment is minimal, the incentive is minimal. In a three-tier copayment structure, generic drugs commonly are assigned to the first-tier with the lowest copayment; whereas, multiple-source, brand-name drugs are assigned to the third tier with the highest copayment.

As the absolute difference in first- and third-tier retail copayments increases, the percent of generic prescriptions increases as shown in Table 28. This trend also is seen in mail service as shown in Table 29.

Coinsurance appears to be a tool that can be used to increase generic drug use. Plans that have a coinsurance component for mail service achieved a 36.4% generic drug use while plans without a coinsurance component achieved 33.4% generic drug use. There was no difference in the results observed for retail prescriptions.

Before the introduction of three-tier copayment

schemes, the primary strategy to encourage generic utilization was to assess a financial penalty to beneficiaries that choose to accept a multi-source brand drug when a generic is available. Traditionally, this penalty was the difference in cost between the generic and brand drug. The intent was to keep the employer's cost the same whether the generic or brand was dispensed. With the introduction of a third copayment tier and the assignment of multi-source brand drugs to that tier, many employers have chosen to eliminate the generic penalty. Financially, the third-tier copayment approximates the amount that the patient would have paid with the penalty.

Requiring members to pay the difference in cost between the brand and generic drug is a commonly used incentive. Plan sponsors differ as to when to apply the penalty. Some require it whenever a generic is available; others do not require it if the doctor specifies the brand drug is required. See the impact of this policy for retail in Table 30 and mail service in Table 31.

SIMPLY SETTING THE  
GENERIC COPAYMENT  
LOWER THAN THE  
BRAND-NAME DRUG  
COPAYMENT CAN  
ENCOURAGE GENERIC  
DRUG UTILIZATION.  
HOWEVER, IF THE DIFFERENCE BETWEEN THE  
BRAND AND GENERIC  
COPAYMENT IS MINIMAL,  
THE INCENTIVE IS  
MINIMAL.

**Table 28: Impact of Copayment Difference on Retail Pharmacy Generic Dispensing**

Difference Between Tier 1 and Tier 3 Copays	Percentage of Retail Prescriptions Dispensed as Generic
\$0 - \$24	42.3%
\$25 +	45.1%

**Table 29: Impact of Copayment Difference on Mail Service Pharmacy Generic Dispensing**

Difference Between Tier 1 and Tier 3 Copays	Percentage of Mail Service Prescriptions Dispensed as Generic
\$0 - \$29	31.3%
\$30 - \$59	33.5%
\$59 +	35.0%

**Table 30: Impact of Generic Penalties on Retail Pharmacy Generic Dispensing**

Generic Penalty Description	Average Percent of Retail Prescriptions Dispensed as Generics
Sometimes Pay Penalty	39.9%
Always Pay Penalty	46.1%

**Table 31: Impact of Generic Penalty on Mail Service Pharmacy Generic Dispensing**

Generic Penalty Description	Average Percent of Mail Service Prescriptions Dispensed as Generics
Sometimes Pay Penalty	33.0%
Always Pay Penalty	36.9%

## APPENDIX: SUPPLEMENTAL DATA

The PBMI survey organizes respondent organizations by major Standard Industrial Classification (SIC) Codes. These codes are based on the first two digits of the employer's primary standard industrial classification code.

Table 32: Industry Segments Created From Respondents' SIC Codes

Industry Segment	First Two Digits of SIC Code
Agricultural, Forestry, and Fishing	01-09
Mining	10-14
Construction	15-17
Manufacturing	20-39
Transport, Communications, and Utilities	40-49
Wholesale Trade	50-51
Retail Trade	52-59
Finance, Insurance, and Real Estate	60-67
Services	70-89
Public Administration	91-97

Table 33: Retail Reimbursement by Geographic Location

Region	Brand Drug		
	Average AWP	Average Fee	Reimbursement Rate
Northeast	85.1%	\$1.98	87.3%
South	85.5%	\$2.03	87.7%
Midwest	85.6%	\$2.09	87.8%
West	85.8%	\$2.18	88.2%
All	85.5%	\$2.05	87.7%

Table 34: Retail Reimbursement by Industry Segment

SIC	Brand Drug		
	Average AWP	Average Fee	Reimbursement Rate
Manufacturing	85.3%	\$2.01	87.5%
Transportation	85.1%	\$1.96	87.3%
Wholesale	85.6%	\$2.11	87.9%
Retail Trade	85.6%	\$2.11	87.9%
Finance	85.5%	\$2.02	87.7%
Services	85.5%	\$2.08	87.7%
Public Admin.	85.5%	\$1.99	87.7%
All Others	85.8%	\$2.06	88.1%
Total	85.5%	\$2.05	87.7%

Table 35: Mail Reimbursement by Geographic Location

Region	Brand Drug		
	Average AWP	Average Fee	Reimbursement Rate
Northeast	79.0%	\$0.37	79.2%
South	79.6%	\$0.45	79.8%
Midwest	79.6%	\$0.54	79.8%
West	79.9%	\$0.76	80.2%
All	79.6%	\$0.52	79.7%



Table 36: Mail Reimbursement Rate by Industry Segment

SIC	Brand Drug		
	Average AWP	Average Fee	Reimbursement Rate
Manufacturing	79.1%	\$0.36	79.2%
Transportation	78.2%	\$0.16	78.2%
Wholesale	79.8%	\$0.53	80.0%
Retail Trade	79.7%	\$0.64	79.9%
Finance	79.6%	\$0.52	79.8%
Services	79.8%	\$0.62	80.0%
Public Admin.	79.9%	\$0.34	80.0%
All Others	80.1%	\$0.74	80.4%
Total	79.6%	\$0.52	79.7%

Table 37: Percentage of Total Rebate Dollars by Industry Segment

Industry Segment	Percentage of Rebate Dollars
Manufacturing	75%
Transportation	78%
Wholesale	75%
Retail Trade	54%
Finance	83%
Services	84%
Public Admin.	78%
All Others	68%
Total	79%

Table 38: Retail Cost Sharing by Industry Segment

SIC	Average Copayments			Percent With Coinsurance
	First Tier	Second Tier	Third Tier	
Manufacturing	\$8.74	\$19.85	\$35.33	43%
Transportation	\$8.41	\$18.24	\$31.36	35%
Wholesale	\$8.21	\$19.29	\$35.36	24%
Retail Trade	\$8.26	\$18.48	\$35.94	39%
Finance	\$9.46	\$20.60	\$35.30	27%
Services	\$8.59	\$18.80	\$35.01	26%
Public Admin.	\$7.33	\$17.29	\$33.75	23%
All Others	\$9.57	\$21.18	\$37.22	16%
Total	\$8.66	\$19.26	\$35.15	30%

Table 39: Mail Service Cost Sharing by Industry Segment

SIC	Average Copayments			Percent With Coinsurance
	First Tier	Second Tier	Third Tier	
Manufacturing	\$17.06	\$38.15	\$63.59	22%
Transportation	\$14.75	\$32.19	\$61.82	27%
Wholesale	\$16.76	\$40.00	\$72.64	12%
Retail Trade	\$15.97	\$37.50	\$72.00	30%
Finance	\$19.20	\$43.50	\$72.95	17%
Services	\$16.28	\$36.10	\$68.49	14%
Public Admin.	\$13.69	\$34.13	\$57.17	9%
All Others	\$18.18	\$38.29	\$70.72	11%
Total	\$16.63	\$37.33	\$67.55	17%

## NOTES

CREATING OPPORTUNITIES  
WITH HEALTHCARE SOLUTIONS



# **Exhibit 17B**

## **Mark Your Calendars for PBMI's Annual Conference: February 21-23, 2007**

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PBMI's Prescription Drug Utilization Management Conference will be held earlier than usual this year – February 21-23, 2007 – at the Pointe Hilton Tapatio Cliffs Resort in Phoenix, Arizona. Hear nationally known experts discuss some of the industry's hottest topics, including:

- Specialty Pharmacy Management
- Transparent Contracting Experiences
- Controlling Workers Comp Drug Costs
- Over-the-counter Drug Strategies
- Consumer Directed Drug Benefit Programs

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# The Prescription Drug Benefit Cost and Plan Design Survey Report | 2006 EDITION





To Our Employer and Health Care Colleagues—

Takeda Pharmaceuticals North America, Inc. is pleased to present you with the *2006 Prescription Drug Benefit Cost and Plan Design Report*. The purpose of this report is to give you a comprehensive overview of U.S. trends in prescription drug coverage, plan design, utilization, and drug costs. The research is conducted annually by the Pharmacy Benefit Management Institute ([www.pbmi.com](http://www.pbmi.com)), and this year, responses to the survey came from 418 employers representing 9.6 million beneficiaries.

Takeda highly values its relationships with you who are so critical to the delivery of quality health care. To help you meet your benefit objectives, we strive to provide you with comprehensive research and development, innovative services, and ongoing support and partnership.

It is in this spirit that we offer you this research, and we hope you find the *2006 Prescription Drug Benefit Cost and Plan Design Report* to be a valuable resource for the coming year.

Cordially,

A handwritten signature in cursive script that reads "Suzanne McDonald".

Suzanne McDonald  
Vice President, Managed Markets  
Takeda Pharmaceuticals North America, Inc.



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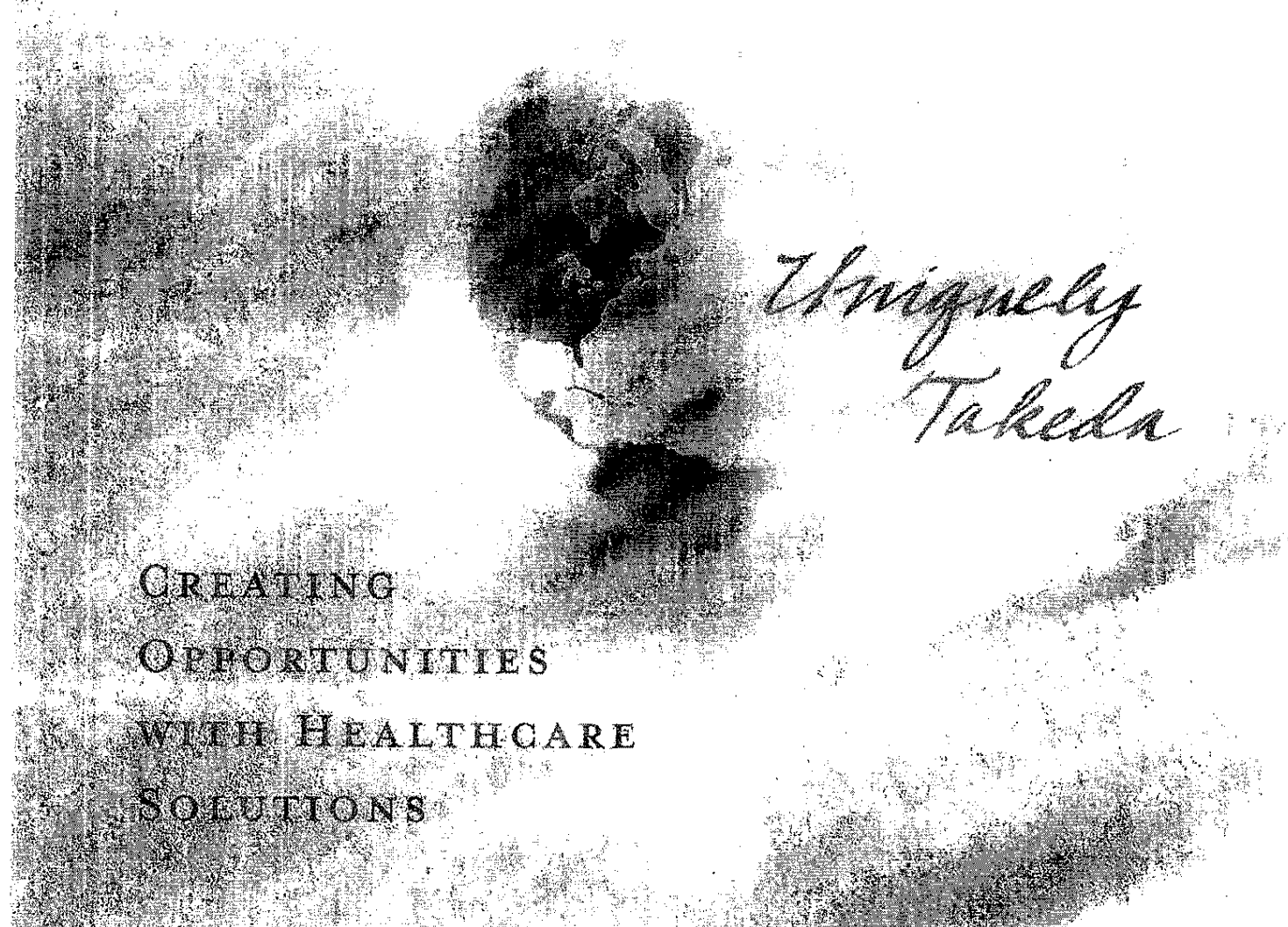
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AMERICAN COLLEGE OF  
OCCUPATIONAL AND  
ENVIRONMENTAL MEDICINE

Dear Reader:

Last year I discussed with you the increased recognition of the value of having a healthy workforce, both in presence on the job and the ability to perform productively. With more and more employers viewing employee health and health care benefits as part of a broader strategy linked to corporate business objectives, the American College of Occupational and Environmental Medicine (ACOEM) continues its research in this arena. In late 2005, ACOEM and the Integrated Benefits Institute (IBI) initiated a research study, funded through a grant from the National Pharmaceutical Council (NPC) to assess the full costs of absenteeism and presenteeism on a company's productivity. ACOEM and IBI, working in strategic collaboration with CorSolutions, Harvard Medical School and the Midwest Business Group on Health (MBGH), are focusing their "*Health and Productivity as a Business Strategy*" (HPS) study on identifying leading chronic conditions, including the impact of medical and pharmacy costs, that drive employer healthcare costs.

The goal of the research is to develop a greater understanding of the total impact of health on the financial bottom line for employers and contribute to industry advancement and the betterment of human health. The HPS is designed to confidentially survey more than 100,000 employees using the Health & Work Performance Questionnaire (HPQ). The HPQ is an online validated productivity measurement survey tool developed by Ron Kessler, Ph.D., of the Harvard Medical School, in conjunction with researchers from the World Health Organization (WHO). Additionally, data analysis on health and pharmacy claims will be provided by CorSolutions and evaluated in conjunction with the HPQ to calculate health care expenditures and provide additional financial factors for calculating operational expenses.

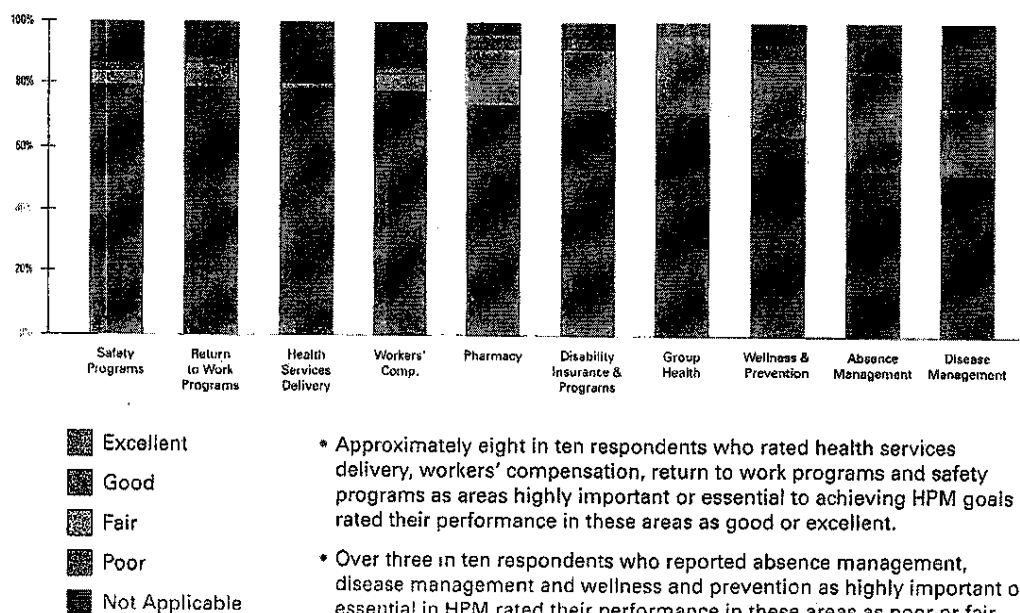
ACOEM and IBI are working jointly on this study which is targeting strategic partners in both the benefits and occupational health functions of five to 10 major corporations for participation. The study is collecting aggregate benefit program information from each corporation, and will bring presenteeism into the "full-cost" framework so that the impact of absence and ill-health at work on productivity loss are understood compared to employer out-of-pocket expense, i.e. medical and pharmacy claims.

As strategic partners in the study, the participating organizations will leverage their expertise in group health, workers' compensation, short-term disability, long-term disability, incidental absence and family medical leave to help determine targeted cost/benefit analysis and plan modeling that may include disease management, EAP or wellness programs.

Phase I of *The Health and Productivity as a Business Strategy* study is scheduled for completion by December 2006. Study outcomes featuring a validated third-party health and productivity snapshot report will be shared with participating employers to help quantify the effects of health problems on productivity. ACOEM and IBI will publish a preliminary report on Phase I with plans to publish final results as well as share findings as part of public presentations once Phase II is completed in early 2006.

One component of the study will be to assess how the results of this study compare to results obtained in previous research conducted with the Benfield Group in 2003. When participants were asked how well they were performing in specific areas, they indicated that their organizations' *largest performance gaps*, relative to importance in achieving health and productivity goals, were in absence management, disease management, and wellness and prevention. Participants report their organizations' *best performance* with respect to achieving health and productivity goals in health services delivery, safety programs, workers' compensation and return-to-work programs as depicted in Figure 1.

Approximately 70% of study participants rated their pharmacy performance as good or excellent in the 2003 study. The current research initiative will take a more in-depth look at pharmacy programs by showing pharmacy claims data by disease category and assessing the effect of benefit programs on claims. Phase I results will be available later this year. An executive summary will be posted on the ACOEM website at [www.acoem.org](http://www.acoem.org).

**Figure 1. Performance in Highly Important or Essential Components**

ACOEM continues to use information gleaned from its research studies for the development of educational materials including *Health and Productivity Management: Harnessing the Full Value of Corporate Health* course and the *Health and Productivity Toolkit*. Information on both of these products can be found at [www.acoem.org](http://www.acoem.org). As other research projects are completed, results will be available on ACOEM's website and be incorporated into educational programming. We look forward to a productive year and the ability to add to the growing health and productivity knowledge base.

*Barry S. Eisenberg*

Barry S. Eisenberg, CAF  
 Executive Director  
 American College of Occupational  
 And Environmental Medicine



Barry S. Eisenberg



Dear Reader,

The bad news is that last year, employer health insurance premiums increased by 11.2 percent—nearly four times the rate of inflation—according to the Henry J. Kaiser Family Foundation. The annual premium for an employer health plan covering a family of four averaged nearly \$10,000, while the annual premium for single coverage averaged \$3,695.

The better news is that drug trend costs are moderating at 6.4 percent in 1999 to 8.4 percent last year according to Medco's *2005 Drug Trend Report*, but the pressure is on to find ways to stem costs without compromising quality and accessibility. According to Express Script's annual *Drug Trend Report*, plan sponsors who used at least one type of cost/quality management tool showed a net cost growth of 5.9 percent; the rate declined to -4.6 percent when two or more tools were used.

As CEO and president of the National Business Coalition on Health, I would like to share the results of an internal survey we conducted with employer groups of fewer than 5,000 employees. The report illustrates the administrative approaches employer groups are taking to stabilize drug costs. I believe that the information will be an interesting supplement to the annual *Prescription Drug Benefit Cost and Plan Design Survey Report*.

When asked about funding arrangements, 69% of respondents, mostly employers with fewer than 5,000 employees, have chosen to self-insure and thereby accept a greater portion of the financial risk. The other 31% are fully insured, leaving the managed care organization to bear most of the risk. The larger the company, the more likely it is to choose self-funding.

Plan sponsors selected self-insurance for a variety of reasons: 97% cite that the model provides the ability to customize the health plan to meet workforce needs, while 90% said it enables them to contract with providers or provider networks to fulfill employee needs. Of least concern is the exemption of self-funded programs from state health insurance premium taxes. Only 9% of respondents have changed their funding status within the last three years, and only 12% intend to do so in the next few years.

The majority of employers (68%) use separate vendors for the administration of medical and pharmacy benefits. Of that group, 53% rely on an external pharmacy benefit manager (PBM), and 32% carve-out the pharmacy benefit to multiple vendors. The minority of respondents (30%) do not use a separate vendor with 80% of them contracting with a single insurance/carrier/managed care organization for both medical and pharmacy benefits.

Changes in contracting with single or multiple vendors have occurred among 18% of respondents with the majority moving to a carve-out model. Most employers said that their motives were based on a desire for greater control over costs and to pay less for benefits. Twenty-two percent expect to change their approach with a near-even split between choosing a carve-out or a carve-in. Again, financial considerations were the biggest factor.

In evaluating a PBM, 77% of respondents indicated that total pharmacy cost management was "important" or "very important," with 58% focusing on price discounting and less than 50% on service/ease of doing business and safety/efficacy. Contrary to respondents' priorities, only 18% rated their PBMs as doing an excellent on price discounting, while the majority had more praises for their PBMs performance in service and efficacy.


Those employers using a separate vendor for pharmacy reported higher levels of satisfaction with their PBMs than those using a single vendor. In addressing total pharmacy cost management, the comparison is 86% versus 66%, respectively, and for price discounting, 86% versus 61%, respectively. Although cost considerations were the most important, 26% indicated they were not aware of an increase in their company's overall prescription drug expenditures from 2003 to 2004. While 80% of employers using separate vendors knew, 58% using a single vendor had the information.



Those using separate vendors also fared better when it came to keeping costs down; 64% reported increases of less than 15% while 49% of those using a single vendor did. Respondents using a separate vendor were more satisfied about their company's drug expenditure growth than those relying on a single vendor. Most employers agreed that increased utilization was the primary culprit for spending growth 2004 to 2004. For those using a single vendor, they also cited price increases and a greater use of branded drugs as cost drivers.

Fifty-seven percent use a broker or agent paid by the insurance carrier, while 24% pay a fee directly to a benefits consultant to help select medical and pharmacy benefits. Of those using an outside advisor, 75% admit that the consultant is "influential" or "highly influential"; companies with fewer than 1,000 employees place an even greater emphasis on an advisor. In addition, employers who use a benefits consultant were more satisfied with their pharmacy expenditure growth than those who relied on a broker/agent or used no one at all.

Overall, the results of the survey indicate that employers using separate vendors for pharmacy and medical benefits are more satisfied with their PBMs' performance and ability to help keep costs down, as well as more tuned into the reasons for cost increases, than those utilizing a single vendor.



Andrew Webber  
President and CEO  
National Business Coalition on Health



Andrew Webber



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# Executive Summary

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## INTRODUCTION

The Pharmacy Benefit Management Institute, LP (PBMI) has conducted a survey of the nation's employers to assess trends in pharmacy benefit management, plan design, and cost issues annually since 1995. Survey data are collected and analyzed to provide employers with a comprehensive overview of the current state of prescription drug coverage cost and plan design issues. Based on responses from 418 employers representing 9.6 million beneficiaries, here's a summary of key research findings.

## KEY FINDINGS

### Pharmacy Reimbursement Decline Continues

Reimbursement for both retail and mail-service pharmacy continues its decade-long decline, which this research has traced since the survey's inception in 1995. Discounts in retail, brand-drug AWP increased by 0.5% from 2004 to 2005. The average retail, brand-drug dispensing fee continued its steady decline, decreasing from \$1.95 in 2004 to \$1.88 in 2005. The average mail, brand-drug AWP discount increased by 0.9% from 21.0% in 2004 to 21.9% in 2005. Average mail, brand-drug dispensing fees decreased from \$0.41 in 2004 to \$0.24 in 2005, the continuation of its steady decline.

### Formulary Adoption Plateaus

The use of formularies appears to have reached a saturation point in 2003, when it hit 92%. It grew to this figure from a level of only 54% of respondents in 1995, with 91% reporting formulary use in 2004 and 89% in 2005.

## Cost Share Changes

Retail copayments increased for all tiers from 2004 to 2005, with each up by 4%. Mail-service co-payments increased by a similar amount for all three tiers. The mail-service second-tier copayment is approaching twice the level of the retail second-tier copayment, compared with 1.6 times in 2001. The earlier minimum differential was designed to encourage mail use, but was resulting in higher net costs to plan sponsors for mail than retail.

The percentage of employers using coinsurance for second-tier retail cost sharing increased from 22% in 2001 to 35% in 2005. Although most employers who use coinsurance generally use it for all drug categories, some employers use coinsurance only for second- or third-tier drug prescriptions. This approach allows plans more flexibility to ensure that patients pay a consistent portion of the benefit cost, while providing an additional incentive to use generic drugs.

The use of deductibles as a way to manage costs has doubled since 2000. Almost 17% of employers reported deductible use in 2005 compared with 8% in 2000. Deductible amounts increased by about 50% for single deductibles and 66% for family deductibles from 2000 to 2004, but are down somewhat in 2005.

A recent trend to help plan sponsors better control costs has been the introduction of a fourth-tier copayment. Although the level of use (44 out of 418 respondents) isn't large yet, it has doubled since 2004. A majority of these employers use this category for specialty drugs. Although the employer continues to pay a comparatively higher share of the cost

of these drugs, the fourth tier allows the employer to collect a somewhat higher copayment for these drugs. When used for lifestyle drugs, the copayment amount is, in many instances, equal to the entire cost of the drug.

## Over-the-Counter Drug Coverage Increases

In 2003, loratadine (Claritin®) became available as an over-the-counter (OTC) product and all prescription versions of the drug were removed from the market. By 2005, the coverage of this OTC product has increased to 13%. Only 9% of plan sponsors cover the OTC version of Prilosec®. While coverage of OTC Prilosec is less than that of Claritin, this difference can be explained because Prilosec is still available as a prescription drug; Claritin is not. This may be due to the availability of generic omeprazole (Prilosec).

## Drug Trend Shows Minor Increase

Survey respondents reported a 7.5% increase in costs from 2004 to 2005. Respondents who indicated that they defined their own benefit plan experienced a 7% increase compared to a 9% increase for respondents who allowed a third party to define their benefit plan.

Average retail generic utilization has increased each year since 2002, from 42% in 2002 to 51% in 2005. Average mail-service generic utilization increased from 32% in 2002 to 39% in 2005. These rates are expected to continue to increase as more drugs become available generically, cost sharing incentives increase, and more and different utilization management programs are implemented.

## Methodology

### IMPLICATIONS OF FINDINGS

Amidst these marketplace changes, successful management of the prescription drug benefit has resulted in the lowest rate of cost increases seen since PBMI began conducting this survey in 1995. The average increase in prescription drug expenditures from 2004 to 2005 was 7.5%. Employers report using many different tools to control the rate of growth in drug costs including:

- Coinsurance utilization for cost sharing
- Multi-tiered formularies
- Increased copayment levels
- Programs to increase medically appropriate generic utilization

Follow-up telephone interviews with plan sponsors illustrate that it takes effort on all fronts—plan design, drug mix, cost sharing and pharmacy reimbursement—to hold down costs. In the employer's voice, here are some comments on cost control:

This report is based upon data collected during the fall of 2005. The data were collected using a survey designed and conducted by PBMI. Based in Scottsdale, Arizona, PBMI provides information and education services to the pharmacy benefit industry. PBMI analyzed the survey data, wrote, and produced this report. PBMI takes full responsibility for its content.

PBMI gratefully acknowledges the support of Takeda Pharmaceuticals North America, Inc. for the provision of a grant to cover costs incurred in the production of this report. Takeda Pharmaceuticals North America, Inc. has no access to the individual responses or raw data gathered, nor do any other third parties. This protects the confidentiality of the survey respondents and ensures the independence and objectivity of this report.

PBMI received 418 completed surveys representing 9,596,807 beneficiaries. The number of beneficiaries reported by a respondent is for the benefit plan for which the survey was completed, not necessarily all the beneficiaries included in all plans offered by the respondent's organization.

### RESPONDENT DEMOGRAPHICS

The breakdown of respondents according to size of employer plan has remained relatively constant since the inception of this survey. The survey respondents are grouped by number of members ranging in size from those with 2,000 or fewer members (20%) to those with more than 50,000 members (11%) as illustrated in Table 1.

The composition of the respondents by geographic region is displayed in Figure 1. The greatest number of respondents

### Renegotiating AWP Discounts With PBM

*"We were one year into a two-year [PBM] contract and we said, 'Listen, there's still a lot of money on the table and we know it. We're renegotiating right now.'"*

### Implementing Coinsurance Copayments

*"We negotiated coinsurance with the union in July 2005 and went to a three-tiered formulary system."*

### Clinical Programs

*"We're putting in more clinical programs. It's a little bit early to tell if they are going to have a major impact. They're not broad sweeping at this point but we're trying to get them into play with our population. The programs include prior authorizations, and quantity limits on drugs for pain management, migraine headaches, and sleep aides."*

*"We have an annual health fair and had over 60% of our employees participate last year, which helped to increase generic use."*

### Mail-order Incentives

*In our plan design, we kept the generic mail-order prices from the prior year and increased the retail preferred and nonpreferred drug copayments by 10%."*

**Table 1. Respondents Grouped By Number of Members**

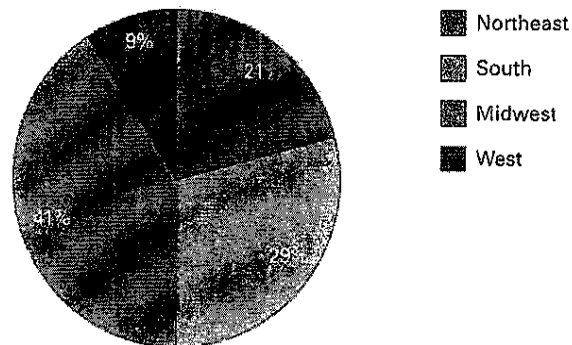
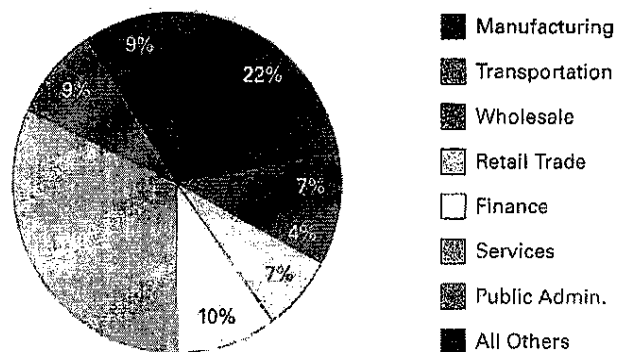
Number of Members	Employers	Employees	Employee Dependents	Retirees	Retiree Dependents	Total Beneficiaries
Unreported	18	0	0	0	0	0
1 - 2,000	83	48,282	25,977	3,265	1,122	78,646
2,001 - 4,000	60	95,311	67,825	6,902	1,923	171,961
4,001 - 6,000	44	102,972	105,726	11,291	5,894	225,883
6,001 - 10,000	54	164,412	209,959	24,230	14,927	413,528
10,001 - 20,000	47	286,454	275,406	54,150	25,987	641,997
20,001 - 50,000	67	786,521	1,052,611	156,763	84,888	2,080,783
50,001 +	45	2,641,611	2,443,517	664,125	234,756	5,984,009
Total	418	4,125,563	4,181,021	920,726	369,497	9,596,807

(41%) are employers headquartered in the Midwest and the smallest number are employers with headquarters in the West (9%).

Employers are assigned to standard industrial classification (SIC) code divisions based on the first two digits of the employer's primary SIC code. About one-third (32%) of the respondents are from the services industry and 22% are from manufacturing. A complete breakdown by industry segment is shown in Figure 2.

Respondents were asked to specify who has primary responsibility for defining the drug benefit: the employer or another entity such as a managed care organization, health care administrator, or insurer. This information allows evaluation of the differences among benefit designs based on whether the employer or a third party is responsible for defining the drug benefit. It is important to note that the data provided by the respondent are for a single plan for which the employer has chosen to respond.

The vast majority of respondents describe their pharmacy benefits as self-defined, as shown in Table 2. This number is consistently in the 80% to 85% range each year. The report discusses the impact of this factor on the survey results in sections where applicable.

**Figure 1. Percentage of Respondents by Geographic Location****Figure 2. Percentage of Respondents by Industry Segments****Table 2. Percentage of Respondents by Plan Design Responsibility**

Organization Responsible for Drug Benefit Design	Percentage of Respondents
Plan Sponsor	81%
Outside Organization	19%

## Research Findings

### PHARMACY REIMBURSEMENT

Discounts in retail, brand-drug AWP increased by 0.5 points from 14.8% in 2004 to 15.3% in 2005. This is the continuation of a steady growth seen over a number of years. Overall, the AWP discount increased by 3.5% points from 1995 to 2005. The average retail, brand-drug dispensing fee continued its steady decline, decreasing from \$1.95 in 2004 to \$1.88 in 2005. The average reimbursement rate, which is a combination of average AWP and average dispensing fee, declined from 87.0% in 2004 to 86.2% in 2005. These trends are shown in Table 3.

Mail-service brand-drug AWP discounts also increased. As shown in Table 4, the average mail, brand-drug AWP discount increased by 0.9% points from 21.0% in 2004 to 21.9% in 2005. Average mail dispensing fees decreased from \$0.41 in 2004 to \$0.24 in 2005, the continuation of its steady decline. The average reimbursement rate, which is a combination of average AWP and average dispensing fee, declined from 79.1% in 2004 to 78.1% in 2005.

### Trends in Reimbursement

In 2001, 44% of employers paid retail pharmacies an AWP of 87% or higher for brand drugs. In 2005, only 5% of employers reported paying an AWP of 87% or higher. Also in 2001, 7% of the

survey respondents reported paying an AWP less than 85%. By 2005, almost half of employers reported paying an AWP of less than 85% (See Table 5). None of the sample reported an AWP this low back in 1995.

**Table 3. Retail Brand Reimbursement**

Year	Average AWP	Average Dispensing Fee	Average Reimbursement Rate
2005	84.7%	\$1.88	86.2%
2004	85.2%	\$1.95	87.0%
2003	85.5%	\$2.05	87.7%
2002	85.9%	\$2.13	88.6%
2001	86.1%	\$2.21	89.3%
2000	86.5%	\$2.31	90.3%
1999	86.9%	\$2.30	91.3%
1998	86.8%	\$2.35	91.9%
1997	87.4%	\$2.32	93.2%
1996	87.9%	\$2.47	95.1%
1995	88.2%	\$2.50	96.5%

**Table 4. Mail-Service Brand Reimbursement**

Year	Average AWP	Average Dispensing Fee	Average Reimbursement Rate
2005	78.1%	\$0.24	78.1%
2004	79.0%	\$0.41	79.1%
2003	79.6%	\$0.52	79.7%
2002	80.3%	\$0.86	80.6%
2001	81.1%	\$1.09	81.6%
2000	81.5%	\$1.15	82.1%
1999	82.6%	\$1.38	83.3%
1998	82.9%	\$1.51	83.9%
1997	83.4%	\$1.61	84.6%
1996	84.4%	\$1.71	85.9%
1995	85.0%	\$1.82	86.8%

**Table 5. Trends in Retail Brand Discounted AWP**

Percent of Respondents	2005	2004	2003	2002	2001
< 84%	4%	5%	4%	2%	N/A
84%	45%	25%	17%	10%	7%
85%	36%	39%	32%	34%	24%
86%	9%	21%	27%	26%	26%
87%	4%	9%	19%	24%	37%
> 87%	1%	1%	1%	5%	7%



When considering survey results based upon the various demographic data available, it appears there is little difference by geographic location as detailed in Table 6. In past surveys, employers headquartered in the West region achieved less deep retail brand reimbursement rates than employers headquartered in other parts of the country.

Employer plan size does provide some advantage. Employer plans with more than 20,000 members achieved retail

reimbursement rates approximately 0.8% points less than that of employer plans with fewer than 2,000 members as shown in Table 7.

Mail-service AWP discounts also have increased over time. In 2001, 44% of employers paid mail-service pharmacies an AWP of 82% or greater for brand drugs. However, by 2005 only 5% of employers had an AWP of 82% or greater. Similarly, 4% of employers in 2001 had an AWP of 77% or less, compared with

46% of employers in 2005. These trends are reported in Table 8.

Although less consistent than for retail, there is some tendency for the smaller group to not receive as large a discount as a larger group, which presents an expectation of more claims volume. The group with fewest beneficiaries only achieved a reimbursement rate of 79.4%, while the second largest group had one of 77.2% as shown in Table 9. Most of the remaining groups were about average.

**Table 6. Retail Reimbursement by Region**

Region	Brand Drugs			Generic Drugs
	Average AWP	Average Fee	Reimbursement Rate	Average Fee
Northeast	84.6%	\$1.84	86.1%	\$1.91
South	84.7%	\$1.87	86.2%	\$1.94
Midwest	84.7%	\$1.89	86.2%	\$1.97
West	84.8%	\$1.99	86.4%	\$2.19
All	84.7%	\$1.88	86.2%	\$1.97

**Table 7. Retail Reimbursement by Number of Members**

Size	Brand Drugs			Generic Drugs
	Average AWP	Average Fee	Reimbursement Rate	Average Fee
1 2,000	85.1%	\$2.02	86.8%	\$2.07
2,001 - 4,000	84.6%	\$1.85	86.1%	\$1.92
4,001 - 6,000	84.5%	\$1.87	86.0%	\$2.00
6,001 - 10,000	84.7%	\$1.91	86.3%	\$1.97
10,001 - 20,000	84.8%	\$1.87	86.4%	\$2.01
20,001 - 50,000	84.5%	\$1.82	86.0%	\$1.86
50,001 +	84.4%	\$1.83	85.9%	\$2.00
Total	84.7%	\$1.88	86.2%	\$1.97

**Table 8. Trends in Mail-Service Brand Discounted AWP**

Percent of Respondents	2005	2004	2003	2002	2001
< 77%	23%	12%	8%	4%	2%
77%	23%	20%	15%	7%	2%
78%	21%	15%	11%	15%	5%
79%	13%	14%	11%	12%	17%
80%	11%	21%	23%	19%	17%
81%	5%	7%	14%	14%	13%
82%	0%	4%	12%	13%	20%
83%	3%	1%	2%	7%	11%
84%	0%	3%	2%	6%	6%
> 84%	2%	4%	3%	3%	7%

**Table 9. Mail Reimbursement by Number of Members**

Size	Brand Drugs			Generic Drugs
	Average AWP	Average Fee	Reimbursement Rate	Average Fee
1 - 2,000	79.3%	\$0.39	79.4%	\$0.39
2,001 - 4,000	78.1%	\$0.23	78.2%	\$0.25
4,001 - 6,000	78.0%	\$0.29	78.1%	\$0.35
6,001 - 10,000	78.1%	\$0.17	78.2%	\$0.22
10,001 - 20,000	78.6%	\$0.28	78.6%	\$0.30
20,001 - 50,000	77.2%	\$0.09	77.2%	\$0.11
50,001 +	78.0%	\$0.30	78.1%	\$0.34
Total	78.1%	\$0.24	78.1%	\$0.26

Requiring patients to get refills through the mail-service pharmacy is one way to guarantee the PBM greater volume and motivate the PBM to offer deeper discounts. Respondents who require mandatory refills by mail received a reimbursement rate of 77.1% while respondents who do not require this received a reim-

bursement rate of 78.4%. Those requiring use of mail for refills have increased from just 11% in 2002 to 20% in 2005.

#### FORMULARY

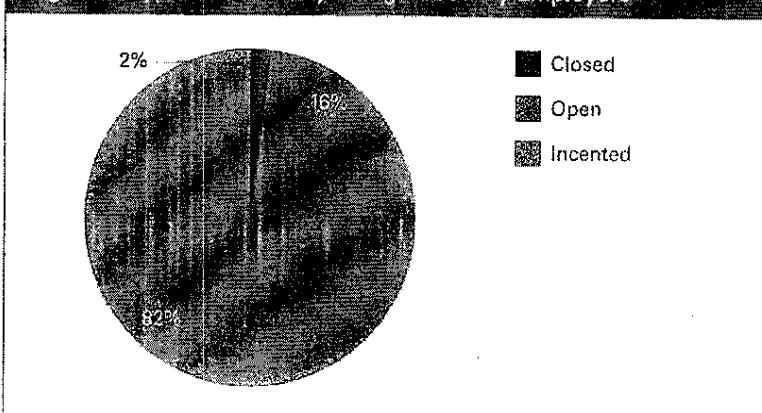
The use of formularies appears to have reached a saturation point. In 1995 only 54% of respondents had reported using a

formulary. This percentage had increased to 74% by 1999. It reached a peak of 92% in 2003 as shown in Table 10.

PBMs group formularies into three categories: closed, open, and incented formularies. A closed formulary forces patients to use the drugs listed on the formulary or incur the entire cost of the prescription. An open formulary doesn't place restrictions on product selection. The traditional open formulary has been largely replaced by the incented formulary concept, which has grown from just 25% of employers in 1999 to 82% of employers in 2005. Open formulary use has decreased from 67% of employers in 1999 to 16% of employers in 2005.

**Table 10. Percentage of Employers Using a Formulary**

Year	Percentage of Employers Using Any Type of Formulary
2005	89%
2004	91%
2003	92%
2002	89%
2001	83%
2000	85%
1999	74%

**Figure 3. Type of Formulary Design Used By Employers**

The use of closed formularies has a very small share of the employer-managed market. In 2005, 2% of the respondents reported using a closed formulary as shown in Figure 3. The percentage of employers who offer closed formularies decreased from 8% in 1999 to 2% in 2005. The breakout by the type of formulary may have stabilized, as there was little change between 2004 and 2005.

The migration from open to incented formularies is the culmination of several factors. As prescription drug costs increase, employers look for creative ways to increase patient cost sharing.



One effective strategy is the introduction of a formulary in which a list of non-preferred drugs is created and higher copayments for these non-preferred drugs are instituted. The creation of the incented or multi-tier formulary provides plan members with a financial incentive to use the preferred drugs while preserving access to the non-preferred drugs. Although patients may not be required to pay the entire cost of a non-preferred drug, they are usually required to pay a higher copayment for non-preferred products.

The traditional, incented formulary has three categories or tiers: generic drugs, preferred brand drugs, and non-preferred brand drugs. However, some plan sponsors have defined other categories of drugs creating fourth and sometimes fifth tiers. In most instances, the purpose of the fourth and fifth tiers is to provide some lower level of benefit for these drugs to its beneficiaries (e.g., lifestyle drugs). In other instances, the purpose is to allow the plan sponsor to define cost sharing in a manner that maintains a level of benefit consistent with the other tiers, while not creating a tier with a lower benefit (e.g., specialty drugs).

Larger employer plans are somewhat more likely to implement a formulary, although this impact of size is less than noted previously. This data is shown in Table 12.

## Incented Formularies Dominate Marketplace

The demise of closed formularies in the employer market is a reflection of the effectiveness of incented formularies. An incented formulary, linked to cost sharing levels or tiers, provides access to a broad list of drugs while managing the plan sponsor's cost of providing the benefit. As shown in Table 11, formulary definitions have changed through the years as utilization management and plan design strategies have grown in sophistication.

**Table 11. Formulary Labels Evolve Over Time**

Descriptor	Time Period	
	Late 1980s to 1990s	2000 Through Present
Open Formulary	Restrictions or penalties were not placed on drugs not included on the formulary because they were not covered.	Used broadly to describe formularies used by employers, health plans, insurance carriers, union groups, and TPAs.
Closed Formulary	Drugs not listed on closed formularies were not covered.	Virtually no closed formularies used by employer segment. Medicaid programs still use closed formularies.
Incented Formulary	Term not yet used.	An open formulary with categorization of drugs into multiple groups or tiers for cost-sharing purposes. The three most common tiers are generic, preferred brand-name, and non-preferred brand-name drugs. Additional tiers for specialty pharmacy and lifestyle drugs such as wrinkle creams that may not be medically essential.

**Table 12. Percentage of Employers Using a Formulary by Number of Members**

Size	Percent With Formulary
Unreported	100%
1 - 2,000	81%
2,001 - 4,000	86%
4,001 - 6,000	95%
6,001 - 10,000	89%
10,001 - 20,000	89%
20,001 - 50,000	92%
50,001 +	86%
Total	89%

### COST SHARING

Employers develop drug benefit plans that share some portion of the drug costs with members, usually based on copayments that vary by tier. In this survey, the average share of retail drug costs borne by members was 27%, with the average share of mail drug costs at 19% as detailed in Table 13.

The terminology PBMs and plan sponsors use to categorize drugs and copayments is relatively standardized. Table 14 illustrates how most plan sponsors group drugs for reimbursement.

Retail copayments increased across all tiers from 2004 to 2005. The copayments increased by 4% in each of the three tiers. Average retail copayments are displayed in Table 15. These increases are somewhat similar for mail as shown in Table 16. From 2004 to 2005 average first-tier mail-service copayments increased by 5%, second-tier increased by 4%, and third-tier by 3%.

**Table 13. Range of Claim Costs Paid by Member**

Point in Range	Retail Cost	Mail Cost
Lowest Percentage	1%	0%
Average Percentage	27%	19%
Highest Percentage	51%	38%

For analysis purposes, PBMI categorized drug copayments according to tier regardless of the classification and number of tiers. However, PBMI excluded responses for which the copayment represented the minimum payment for plans with a coinsurance. In PBMI's judgment, the minimum copayment artificially reduced what PBMI believes is the average copayment. This is a change in how this value was calculated in years prior to 2005.

To provide some perspective about the scope of change over the past four years, PBMI reports the distribution of second-tier copayments for retail in Table 17 and mail in Table 18 for the past 5 years. The percentage of employers who use retail second-tier copayments greater than \$20 increased by 4 points to 39%, its highest

level yet. For mail service, the percentage of employers who use second-tier copayments of \$40 or greater is 64% in 2005, up from 61% in 2004.

Employers understand that cost sharing is a valuable tool to encourage patients to behave in certain ways. For example, one of the purposes of having multiple copayment tiers is to encourage generic drug use. Today, the average retail third-tier copayment (the tier in which most plans categorize multi-source brand drugs) is more than four times the first-tier copayment (the tier in which most plans categorize generic drugs) as contrasted to only three times the first-tier copayment in 1998. This difference gives plan members a significant incentive to use generic drugs.

**Table 14. Common Plan Designs for Multi-Tier Copayments**

Tier	Two-Tier Design	Three-Tier Design	Three-Tier Design	Four-Tier Design
First Tier	Generic	Generic	Generic	Generic
Second Tier	Brand	Single Source Brand	Preferred Brand	Preferred Brand
Third Tier	NA	Multiple Source Brand	Non-Preferred Brand	Non-Preferred Brand
Fourth Tier	NA	NA	NA	Biotech drugs, lifestyle, nonformulary, or other high cost drugs

**Table 15. Average Retail Copayment Amounts for All Respondents**

Survey Year	Copayment Amounts		
	Average First Tier	Average Second Tier	Average Third Tier
2005	\$9.53	\$21.61	\$39.06
2004	\$9.14	\$20.71	\$37.45
2003	\$8.66	\$19.26	\$35.15
2002	\$8.33	\$17.57	\$33.23
2001	\$7.68	\$16.06	\$30.51
2000	\$7.17	\$14.14	\$27.35

**Table 16. Average Mail-Service Copayment Amounts for All Respondents**

Survey Year	Copayment Amounts		
	Average First Tier	Average Second Tier	Average Third Tier
2005	\$17.95	\$41.65	\$77.05
2004	\$17.18	\$39.90	\$74.85
2003	\$16.63	\$37.33	\$67.55
2002	\$14.61	\$31.21	\$60.61
2001	\$12.60	\$26.01	\$55.23
2000	\$10.78	\$21.29	\$45.73

In the past, employers incented patients to use mail service by keeping the mail-service copayments low relative to retail copayments as mail service was recognized as the lowest cost distribution channel. However, employers have learned that mail service will not produce savings for the employer unless copayments are structured appropriately. Although mail order drug costs are lower, the lower copayments established to increase mail service utilization resulted in mail-service prescriptions actually costing the employers more than retail prescriptions.

In an attempt to correct this problem, plan sponsors have increased mail-service copayments more quickly than retail copayments over the past few years. The mail-service second-tier copayment is approaching twice the level of the retail second-tier copayment as compared with 1.6 times in 2001.

### Three- or More Tier Copayment Designs

The use of a three- or more tier plan design, in which the tiers are based on formulary status, continues to gain favor among employers. In 1998, only 6% of employers reported the use of this three- or more plan design. The percentage of employers using a three- or more tier plan design has continued to increase from 46% in 2001 to 76% in 2005. It is expected that the industry will continue to see growth in the percentage of employers

**Table 17. Distribution of Employer Retail Second-Tier Copayments by Dollar Amount**

Copayment by Dollar Amount	2005	2004	2003	2002	2001
< \$10	6%	6%	5%	7%	10%
\$10-\$11	8%	8%	8%	11%	12%
\$12-\$13	1%	1%	2%	4%	8%
\$14-\$15	10%	15%	21%	24%	27%
\$16-\$20	35%	36%	35%	38%	34%
> \$20	39%	35%	29%	17%	10%

**Table 18. Distribution of Mail-Service Second-Tier Copayments by Dollar Amount**

Copayment by Dollar Amount	2005	2004	2003	2002	2001
<\$15	7%	6%	5%	11%	18%
\$15-\$19	3%	4%	6%	7%	10%
\$20-\$24	8%	8%	8%	15%	18%
\$25-\$29	3%	3%	8%	7%	9%
\$30-\$34	11%	15%	17%	18%	19%
\$35-\$39	5%	3%	3%	3%	3%
\$40-\$49	26%	25%	25%	25%	17%
\$50-\$59	19%	22%	14%	10%	5%
\$60 +	19%	14%	13%	4%	2%

offering three-tier or more plan designs. However, the most recent trend is to even more tiers, as noted below.

PBMs and managed care organizations periodically propose new cost sharing schemes with more than three tiers to help plan sponsors better control costs. Plan sponsors have been relatively slow to adopt these new schemes. This year only about 10% of respondents reported using a fourth tier for cost sharing, although

this was double the number in 2004.

A majority of these employers use the fourth tier for specialty drugs. Although the employer continues to pay a comparatively higher share of the cost of these drugs, the fourth tier allows the employer to collect a somewhat higher copayment. When used for lifestyle drugs, this copayment amount is in many instances equal to the entire cost of the drug.

## Creating Incentives to Increase Adherence

Advances in pharmacologic treatment of many diseases have improved greatly the prospects of a longer life for millions of Americans suffering with chronic illness. Many of these prospects are substantially dimmed by one important reality: Noncompliance or lack of adherence.

Poor medication adherence can take many forms: omission of doses, increasing doses, decreasing doses, and not following dosing intervals. Frequently cited causes of noncompliance are outlined in Figure 4.

### Plan Design Support

Benefit design can encourage or discourage adherence. As PBMI's findings show, many employers now use incentive-based formularies to control drug costs. A number of employers have announced plan design changes that reduce cost barriers to maintenance medications to increase adherence to drug therapies and thus lower overall health care costs.

University of Michigan began a two-year pilot program in June 2006 to

waive co-pays for certain generic prescription drugs that control blood sugar, blood pressure, cholesterol, depression, and reduce the risk of heart and kidney problems. It also will reduce co-pays 25% to 50% for brand-name equivalents of those drugs. The university anticipates the program will generate less than \$100,000 in administrative costs, and increase diabetes-related drug costs by \$800,000. Officials believe the investment will be offset by a lowering of other health care costs for the patients involved.

### Value of Coinsurance

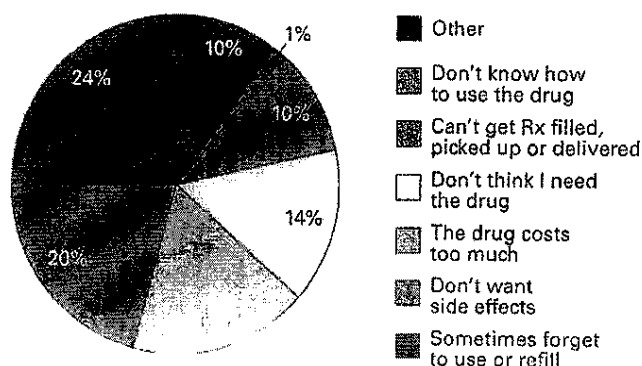
Cingular Wireless (Cingular) was facing increasing drug expenditures for its employee population. The company's three-tier plan design was adequately controlling costs but Cingular wanted to bring employees into a partnership to better manage drug expenditures. Cingular's employees are widely dispersed across the country and younger in average age than most commercially insured groups. The group also had a low mail-order pharmacy utilization rate.

Cingular's goal was to manage the rate of increase in prescription drug expenditures by changing drug purchasing behavior while preserving the quality of the drug benefit program. To achieve this, an effective drug benefit plan design needed to:

- Create sustained employee behavior change to purchase the lowest-cost, effective medication;
- Keep most prescriptions affordable with a maximum coinsurance per script and an annual out-of-pocket limit; and
- Encourage adherence to maintenance medication regimens.

Cingular implemented a four-tier coinsurance plan design with a minimum and maximum cost per script and an annual out-of-pocket limit. The fourth or personal choice tier allows plan members to purchase personal choice drugs such as hair loss products, wrinkle treatment drugs, and depigmenting agents at the plan's discounted cost. Table 19 shows the coinsurance structure.

**Figure 4. Reasons for Poor Medication Adherence**



Source: Stambaugh, T. (2006, April) Prepared with data from Boston Consulting Group analysis and Harris Interactive 10,000 Patients Survey. The Importance of Medication Adherence. Presented at Pharmacy Benefit Management Institute Prescription Drug Utilization Management Conference, Scottsdale, AZ.

**Table 19. Cingular's Coinsurance Structure**

Tier	Retail			Mail		
	Percentage	Script Minimum	Script Maximum	Percentage	Script Minimum	Script Maximum
Generic	20%	\$10	\$75	20%	\$15	\$75
Formulary	30%	\$20	\$100	30%	\$30	\$100
Non-formulary	40%	\$30	\$125	40%	\$45	\$125
Personal Choice	100%	None	None	100%	None	None

The annual out-of-pocket limit is \$1,500 per person and \$3,000 per family.

### Impact and Results

The new coinsurance plan design was implemented January 1, 2004 for 19,500 non-bargained employees. The plan design improved compliance with drug regimens for chronic conditions as shown in Table 20.

The annualized savings resulting from changed Cingular member behavior in 2004 was \$2,821,500.

In addition to these employer examples, there are several published studies that illustrate the impact of plan design on adherence.

**Table 20. Plan Design Increases Adherence**

Disease State	Increase in Days Supplied Dispensed	Increased in Number of Scripts Filled
Asthma	13.6%	16.7%
Diabetes (includes drugs and supplies)	21%	23.5%

### Resources In the Literature

#### Cost Sharing Changes

Gold, D. P., Joyce, G.F., Escarce, J. J., Pace, J.E., Solomon, M.A., Laouri, M., Landsman, P.B., & Teutsch, S.M. (2004). *The Journal of the American Medical Association*, 291, 2344-2350.

#### Impact of Plan Design on Adherence

Shrank, W.H., Hoang, T., Ettner, S.L., Glassman, P.A., Nair, K., DeLapp, D., Dirstine, J., Avorn, J., & Asch, S.M. (2006). The Implications of Choice. *Archives of Internal Medicine*, 166, 332-337.

#### Three-tier Plan Designs

Shrank, W. H., Young, H., Ettner, S.L., Glassman, P., Asch, S.M. & Kravitz, R.L. (2005).

Do the Incentives in 3-Tier Pharmaceutical Benefit Plans Operate as Intended? Results From a Physician Leadership Survey. *American Journal of Managed Care*, 11, 16-22.

#### Value of Reduced Copayments

Goldman, D.P., Joyce, G.F., & Karaca-Mandiz, P.K.. (2006).

Varying Pharmacy Benefits With Clinical Status: The Case of Cholesterol-lowering Therapy.

*American Journal of Managed Care*, 12, 21-28.

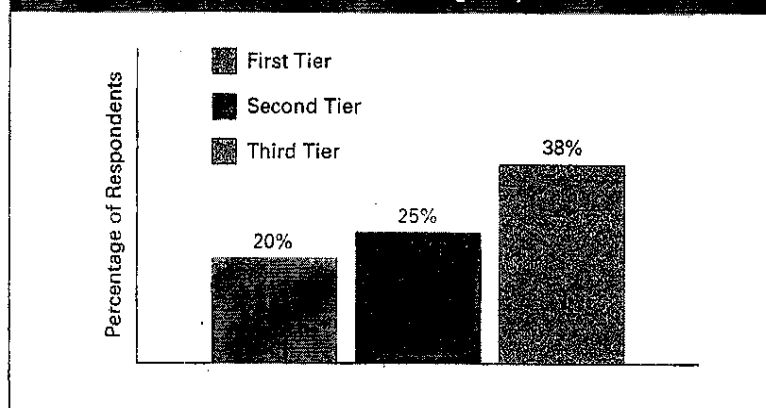
Dr. Goldman of the RAND Corporation can be reached at dgoldman@rand.org.

### COINSURANCE

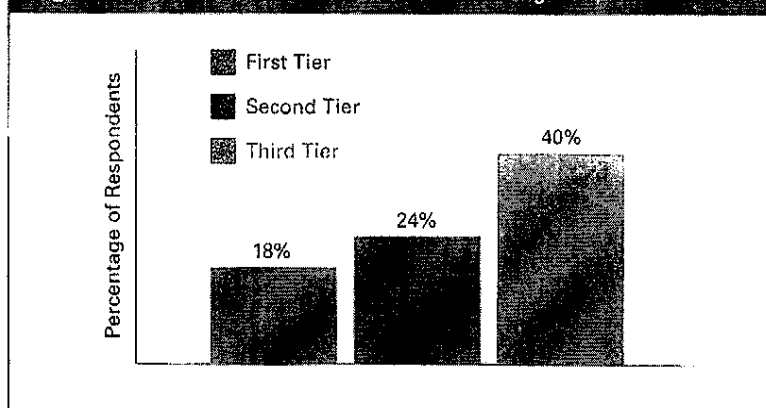
Although most employers who use coinsurance generally use it for all drug categories, some employers use coinsurance only for second- or third-tier drug prescriptions. The percentage of employers using coinsurance for second-tier retail

cost sharing increased from 22% in 2001 to 35% in 2005. This approach for the second and third tiers allows plans more flexibility to ensure that patients pay a consistent portion of the benefit cost, while providing an additional incentive to use generic drugs.

**Figure 5. Retail Coinsurance Percentages by Tier**



**Figure 6. Mail-Service Coinsurance Percentages by Tier**



**Table 21. Retail Cost Sharing by Geographic Region**

Region	Average Copayments			% With Coinsurance
	First Tier	Second Tier	Third Tier	
Northeast	\$9.08	\$19.61	\$36.08	23%
South	\$9.90	\$23.12	\$42.01	31%
Midwest	\$9.20	\$19.44	\$36.05	42%
West	\$8.81	\$20.13	\$36.63	44%
All	\$9.53	\$21.61	\$39.06	35%

Coinsurance often is used in combination with a minimum and or maximum copayment amount. Some respondents use one amount, while others use both the minimum and maximum. The average second-tier minimum copayment for coinsurance plans is less than the average copayment for respondents with copayment plans (\$19.44 vs. \$21.61). The average maximum copayment of \$75.42 for the second tier is nearly four times the average minimum copayment. On average, beneficiaries pay about 20% of the cost of their retail prescription for drugs in the first tier, 25% for drugs in the second tier, and 38% for drugs in the third tier as shown in Figure 5. Employers are using the three-tier structure and differentiating the coinsurance percentage for each tier. Using a higher percentage coinsurance for the third tier increases the incentive to use lower cost drugs in the first tier.

Coinsurance is used less frequently for mail service. In fact, only 23% of the respondents have a coinsurance component for second-tier mail service prescriptions although this has nearly doubled from the 12% in 2002. While the barriers related to using coinsurance in mail service have been eliminated at most mail-service pharmacies, many employers are still reluctant to implement this feature for mail service. On average, beneficiaries pay 18% of the cost of their mail prescription for drugs in the first tier, 24% for drugs in the second tier, and 40% for drugs in the third tier (Figure 6).

For retail prescriptions, the South tends to have higher copayments than the other regions while the West uses coinsurance more frequently than the other regions (see Table 21). For retail prescriptions, larger employers tend to be more frequent users of coinsurance (see Table 22). For mail-service prescriptions, copayments and coinsurance amounts are highly variable as shown in Table 23.



Employers who define their own benefit plans are more likely to use coinsurance. Forty-percent of respondents who defined their own plans use coinsurance as opposed to 13% of the respondents whose plans are defined by other parties. PBMI hypothesizes that many of the respondents who use a third-party to define their benefit plan are using managed care organizations. Traditionally, managed care organizations (MCOs) are less frequent users of coinsurance.

#### Deductibles

The use of deductibles as a way to manage costs has doubled since 2000. Almost 17% of employers reported deductible use in 2005 compared with 8% in 2000. Deductible amounts increased by about 50% for single deductibles and 66% for family deductibles from 2000 to 2004, but are down somewhat in 2005, as shown in Figure 7.

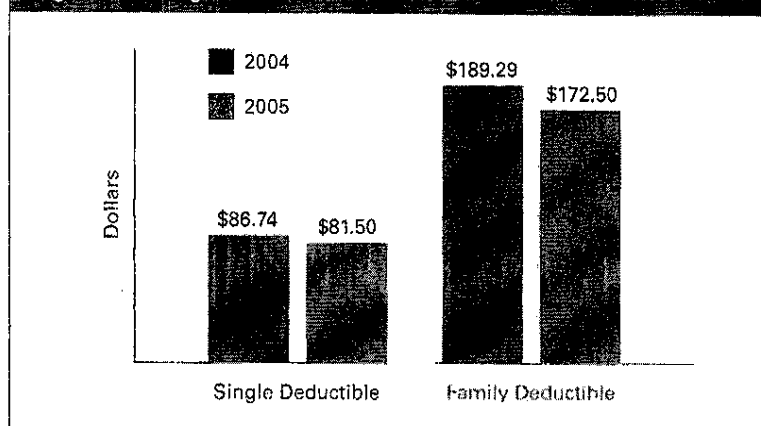
**Table 22. Retail Cost Sharing by Number of Members**

Size	Average Copayments			% With Coinsurance
	First Tier	Second Tier	Third Tier	
Unreported	\$10.17	\$20.92	\$35.23	40%
1 - 2,000	\$10.00	\$21.86	\$42.65	25%
2,001 - 4,000	\$10.03	\$22.13	\$39.75	34%
4,001 - 6,000	\$9.19	\$21.71	\$38.42	30%
6,001 - 10,000	\$8.24	\$17.27	\$35.42	41%
10,001 - 20,000	\$9.93	\$21.67	\$38.69	35%
20,001 - 50,000	\$8.87	\$18.88	\$33.15	45%
50,001 +	\$9.04	\$20.66	\$38.39	38%
Total	\$9.53	\$21.61	\$39.06	35%

**Table 23. Mail-Service Cost Sharing by Number of Members**

Size	Average Copayments			% With Coinsurance
	First Tier	Second Tier	Third Tier	
Unreported	\$19.58	\$43.75	\$84.55	23%
1 - 2,000	\$18.51	\$40.82	\$80.17	18%
2,001 - 4,000	\$19.50	\$44.89	\$81.74	21%
4,001 - 6,000	\$16.85	\$42.44	\$72.97	19%
6,001 - 10,000	\$16.16	\$36.55	\$67.94	18%
10,001 - 20,000	\$19.71	\$44.79	\$78.52	23%
20,001 - 50,000	\$16.18	\$35.10	\$63.31	33%
50,001 +	\$17.56	\$43.88	\$81.49	24%
Total	\$17.95	\$41.65	\$77.05	23%

**Figure 7. Changes in Deductible Amounts from 2004 to 2005**



### DRUG COVERAGE

For the past several years, PBMI surveyed plan sponsors about their coverage decisions for many different drugs. The survey simply asked whether these drugs were covered. PBMI has noted little change in the answers over the past few years. Plan sponsors decided which drugs to cover and, for the most part, nothing was causing them to change their decisions.

Although plan sponsors are not changing the drugs that they cover, they are changing how they cover those drugs. Several issues impact specific drug coverage decisions. First, some of the new drugs being introduced are not viewed as being significantly better than their predecessors. Rather than automatically paying for

these drugs, plan sponsors want their beneficiaries to try the less expensive, first generation drugs before moving to the newest agents on the market. This is primarily accomplished through step therapy or prior authorization programs. Second, some of these drugs have now become available over-the-counter (OTC). Traditionally, plan sponsors do not cover OTC products. Plan sponsors are deciding whether they will cover OTC drugs one product at a time. They also are deciding whether they will cover prescription drugs that have therapeutically equivalent, OTC alternatives. Third, the introduction of additional cost sharing tiers (e.g., third and fourth tiers), provides plan sponsors with options. Rather than excluding certain drugs,

these drugs can be moved to higher tiers providing patients with an incentive to use the preferred products that in some classes are OTC drugs.

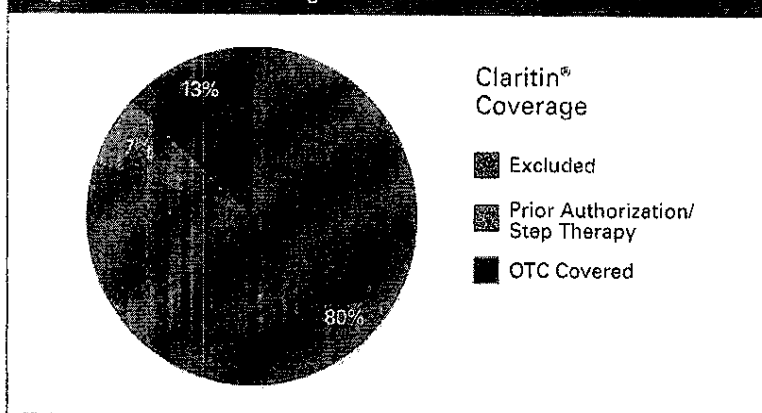
PBMI surveyed plan sponsors about two groups of drugs: nonsedating antihistamines and proton-pump inhibitors. These categories are some of the highest cost categories for many plan sponsors and are the focal point of many management activities.

### Nonsedating Antihistamines

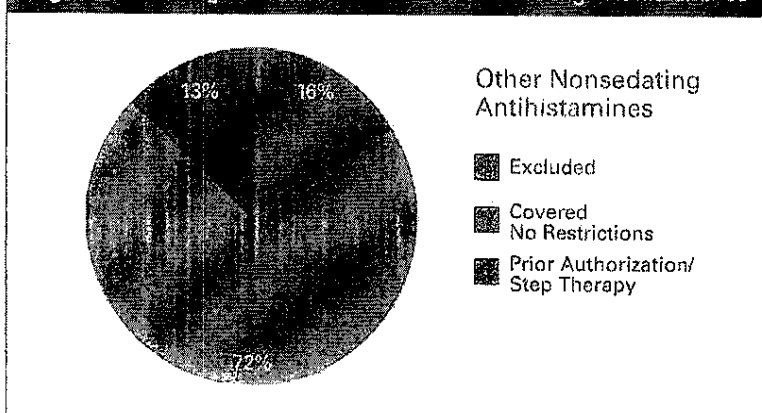
Nonsedating antihistamines such as Allegra®, Zyrtec® and Claritin®, provide allergy relief without the sedating effect of older antihistamines such as Benadryl®. In 2003, loratadine (Claritin®) became available as an OTC product. All prescription versions of the drug were removed from the market. Figure 8 shows the coverage status of loratadine by percentage of plan sponsors. Coverage has increased from 10% in 2003 to 13% in 2005.

The availability of a nonsedating antihistamine in an OTC form is important because it provides plan sponsors with a less expensive coverage option. Regardless of whether a plan chooses to cover the OTC product, the plan may choose, among other options, to exclude prescription nonsedating antihistamines (see Figure 9). Sixteen percent of plan sponsors have chosen to exclude the other nonsedating antihistamines, up from 12% in 2003. However, the percentage of plan sponsors who include these drugs in a prior authorization program increased from 6% in 2003 to 13% in 2005.

**Figure 8. Claritin® Coverage Decisions**



**Figure 9. Coverage Decisions for Other Nonsedating Antihistamines**





## Drug Safety Remains Critical Issue

The number of prescription drugs removed from the market in the past few years underscores the importance of drug safety monitoring.

"There was a tremendous increase in U.S. Food and Drug Administration activity to increase the safety of prescription drugs from 2004 to 2005," reports Doug Long, vice president of industry relations for IMS Health. "The number of Black Box warnings increased nearly five fold while advisories more than doubled." FDA warnings are issued whenever a risk or problem is suspected, he added.

The market withdraw of several drug products has triggered increased interest in the safety of FDA-approved prescription drugs by employers and patients alike. One of the critical aspects of pharmacy benefit management is the ongoing monitoring of prescription drug safety.

Safety is a consideration in formulary decision making so that products placed on formularies have clinical merit and reduce drug-related problems for patients. There are many effective drug benefit management strategies to help ensure formulary drugs are used as safely as possible as shown in Table 24.

Table 24. Strategies to Optimize Safety	
Elements of Therapy Requiring Oversight	Management Strategy Options To Include in Plan Design
Prescribing Consistent with FDA-approved Drug Indications	Step Therapy Protocols Prior Authorization Example: Use step therapy protocols to only reimburse for injectable drugs for treatment of psoriatic arthritis after oral agents fail. This guards against use of therapy with long-term implications for patients' immune systems.
Dosing	Quantity Limits Days' Supply Limits Example: Use days' supply limit to manage use of sleep aides to guard against chemical dependence.
Duration of Therapy	Quantity Limits Days' Supply Limits Retrospective Review of Excessive Utilization Example: Use quantity limits to ensure Oxycontin® is only used for the treatment of patients with moderate to severe pain who are expected to need continuous opioids for an extended period. Limiting the quantity received per month allows the patient and prescriber to evaluate the dosage each month and determine if regimen changes are necessary.

Plan sponsors should continue to call on their PBMs and pharmacy and therapeutics committees to monitor the safety of both traditional therapies and newly approved prescription drugs.

### Online Resources

A variety of consumer and professional Web sites focus on drug safety issues:

**healthfinder** – healthfinder® is an award-winning Web site for consumers, developed by the U.S. Department of Health and Human Services together with other federal agencies. Since 1997, healthfinder® has been recognized as a key resource for finding the best information on the Internet. healthfinder® links to carefully selected government and nonprofit health and human services information from more than 1,500 health-related organizations. [www.healthfinder.gov](http://www.healthfinder.gov)

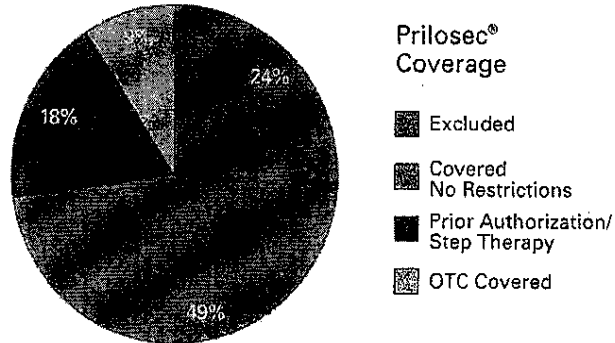
**MedlinePlus** – The National Library of Medicine, a part of the National Institutes of Health, created and maintains MedlinePlus to assist in locating authoritative health information. The pages contain carefully selected links to Web resources with information for health professionals. <http://medlineplus.gov/>

**U.S. Food and Drug Administration** – Detailed information about drug safety from the FDA can be found at <http://www.fda.gov/medwatch/index.html>.

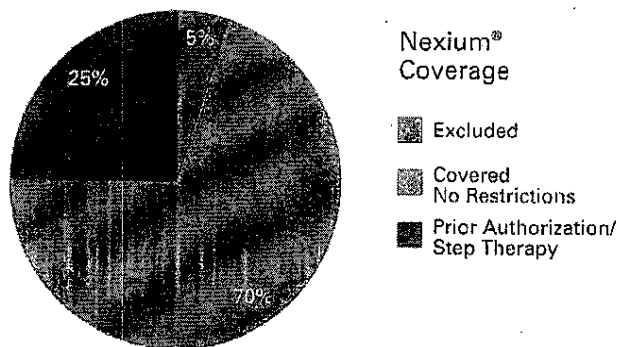
### Proton-Pump Inhibitors

Proton-pump inhibitors (PPIs) are used to treat ulcers and related GI disorders. Although prescription Prilosec® is now available as an OTC product, 24% of plan sponsors exclude coverage as displayed in Figure 10. Many plan designs don't cover prescription products for which there is an OTC equivalent. Only 9% of plan sponsors cover the OTC version of Prilosec, compared to the 13% that cover the OTC Claritin. While the percentage of employers that cover OTC Prilosec is less than Claritin, this difference may be due to the availability of

**Figure 10. Prilosec® Coverage Decisions**



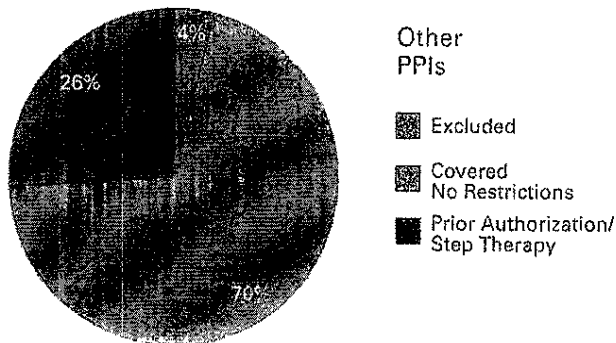
**Figure 11. Nexium® Coverage Decisions**



Prilosec as both a brand and a generic prescription drug, while Claritin is not.

Following the introduction of OTC and generic Prilosec® a next generation PPI called Nexium® became available. Perhaps as a result of published concerns that this new product is only slightly more effective than the previous generation of products, 5% of the plan sponsors have chosen to exclude Nexium as illustrated in Figure 11. In addition, 25% now require prior authorization or step therapy before it can be used, an increase from 16% in 2003. This change indicates a desire to encourage patients to use older, less expensive products first.

**Figure 12. Other PPI Coverage Decisions**



There are several other PPIs available and in general, coverage is similar to Nexium as shown in Figure 12.

**UTILIZATION PATTERNS**

PBMI collects a limited amount of utilization data to quantify the impact of various benefit plan design elements on utilization. Survey respondents reported a 7.5% increase in costs from 2004 to 2005. Respondents who indicated that they defined their own benefit plan experienced a 7% increase compared to a 9% increase for respondents that allowed third parties to define their benefit plan.

**Mail Service Utilization**

Ninety-five percent of respondents reported that they offer a mail pharmacy. Employers reported a broad range in the percentages of total prescriptions dispensed through the mail-service pharmacy as illustrated in Table 25.

Mail-service use can be encouraged through the use of cost sharing incentives or by requiring that refills for maintenance

drugs be dispensed through the mail-service pharmacy. Mandatory use of mail for refills has nearly doubled from 11% in 2002 to 20% in 2005.

Mail service is provided slightly less in the Midwest and slightly more in the Northeast and West. There is a much lower use of mandatory mail service in the West as shown in Table 26.

Mail service is provided at a somewhat lower level in the Transportation and Retail industries. It is mandatory for none of the employers in the Wholesale category and at lower levels for Public Administration and Services as detailed in Table 27.

Table 28 illustrates the impact of mandatory mail-service use on refilling maintenance prescriptions. Mail-service utilization more than doubled when mail service is required for maintenance prescriptions.

**Generic Utilization**

One of the most effective strategies to reduce drug benefit costs is to increase generic drug utilization. Generic drugs, as defined by the U.S. Food and Drug Administration (FDA), are the chemical equivalents of their brand-name counterparts and therefore identical in terms of safety and effectiveness. Generic drugs are typically much less expensive than their brand-name counterparts.

Average retail generic utilization increased from 47% in 2004 to 51% in 2005 as seen in Table 29. Average mail-service generic utilization increased from 38% in 2004 to 39% in 2005. These rates are expected to continue to increase as more drugs become available generically, cost sharing incentives increase, and more utilization management programs are implemented to encourage generic drug utilization.

**Table 25. Range of Mail-Service Utilization**

Point in Range	Percentage of Total Prescriptions Dispensed by Mail-Service Pharmacy
Lowest Use Percentage	0.2%
Average Use Percentage	18.3%
Highest Use Percentage	62.0%

**Table 26. Mandatory Mail by Region**

Region	Mail Service	% Mandatory
Unknown	95%	17%
Northeast	98%	19%
South	95%	20%
Midwest	93%	23%
West	97%	9%
All	95%	20%

**Table 27. Mandatory Mail by SIC**

SIC	Mail Service	% Mandatory
Manufacturing	98%	28%
Transportation	89%	32%
Wholesale	100%	0%
Retail Trade	93%	23%
Finance	100%	28%
Services	90%	16%
Public Admin.	100%	14%
All Others	97%	11%
Total	95%	20%

**Table 28. Impact of Mandatory Mail Service on Mail-Service Utilization**

Mail Service Status	Percentage of Total Prescriptions Dispensed by Mail Service Pharmacy
Mandatory Mail	32%
Voluntary Mail	14%

## Effective Benefit Management Strategies Work For Specialty Pharmacy

Fifty-nine percent of survey respondents offer a specialty pharmacy benefit. This number will continue to increase as employers are forced to underwrite the costs of the high cost drug therapies. The growth and challenges of specialty pharmacy are continuing at an accelerating pace. Specialty pharmacy focuses on the treatment of high-cost chronic diseases where drug therapy either 1) prevents disease progression, or 2) slows the onset of serious clinical complications of the disease, one of which is premature death.

IMS market projections estimate that U.S. specialty drug expenditures were \$42 billion in 2005. This enormous amount is the result of therapies that range in cost from treating multiple sclerosis at \$12,000 per patient per year to treating hemophilia at \$120,000 per patient per year, based on data from the July/August 2004 issue of Specialty Pharmacy.

Managing the economics of specialty pharmacy drugs is analogous to managing the oral medications typically dispensed by retail and mail-order pharmacies. The same tools used to manage the cost of and utilization of acute and chronic therapies can be employed for specialty pharmacy.

**Step 1: Find a Partner** Many pharmacy benefit managers (PBMs), including Caremark, Express Scripts, Inc., Medco Health Solutions, and Walgreens Health Initiatives, have their own specialty pharmacy divisions that they have built or acquired. There are several independent companies including The Apothecary Shops, Icore Healthcare, IVR, and McKesson Specialty.

**Step 2: Develop a Plan Design** Developing a plan design for specialty pharmacy medications will help to ensure beneficiaries get specialty therapies when needed while managing the payer's long-term financial risk. The majority of U.S. employers are now covering the majority of specialty pharmacy drugs in the fourth or highest copayment tier. Employees and retirees are best served by having a plan design just for specialty that creates coinsurance copayments with out-of-pocket maximums.

**Step 3: Implement Clinical Management** Specialty pharmacy drugs are currently used to treat a short list of conditions including rheumatoid arthritis, multiple sclerosis, hepatitis, hemophilia, oncology, pain management, growth hormone disorders, and infertility. The management of each disease state calls for a customized set of clinical programs and tools. Frequently used programs include prior authorization, step therapy, proactive refill management, adherence and persistency oversight, waste management, and side effect management. Customized clinical interventions appropriate for each condition will manage drug expenditures, improve patient outcomes, and help curb total medical costs.

**Step 4: Implement and Communicate** Specialty pharmacy programs and benefit changes can have a dramatic impact on the patient and his or her relationship with the provider. Detailed and frequent communication to providers, pharmacists, and patients is absolutely essential for successful implementation and ongoing benefit management. Effective communication also maintains patient satisfaction.

**Step 5: Evaluate** Successful specialty pharmacy programs transition patients to the appropriate distribution channel for their drug regimens. Ongoing evaluation of the program will allow employers to realize savings and monitor trends so improvements in the specialty program can be made when needed.

### Online Resources

In addition to specialty pharmacy organization and pharmacy benefit manager Web sites, visit these sites for more information:

Agency for Healthcare Research and Quality  
[www.ahrq.gov](http://www.ahrq.gov)

Biotechnology Healthcare Magazine  
[www.biotechnologyhealthcare.com](http://www.biotechnologyhealthcare.com)

National Guideline Clearinghouse  
[www.guideline.gov](http://www.guideline.gov)

As shown in Table 30, there is a broad range of generic dispensing rates for both mail service and retail. For those employers with the highest rates of generic utilization, there may be unique features that allow them to reach these levels of generic dispensing. Mail service generally has lower generic dispensing rates because the drugs most commonly dispensed through mail are not available generically.

Employers can encourage generic utilization in several ways. This includes cost sharing design, generic detailing and education of the prescriber network, and beneficiary education. For example, simply setting the generic copayment lower than the brand-name drug copayment can encourage generic drug utilization. However, if the difference between the brand and generic copayment is minimal, the incentive is minimal. In a three-tier copayment structure, generic drugs commonly are assigned to the first tier with the lowest copayment, while multiple-source brand-name drugs are typically assigned to the third tier with the highest copayment.

As the absolute difference in first- and third-tier retail copayments increases, the percent of generic prescriptions increases as shown in Table 31. Those employers with the lower copay difference also experienced a higher growth in annual per member costs (9.5%) than those with the higher differential (6.9%). The pattern for higher generic dispensing when the copay differential is higher is also seen in mail service as shown in Table 32.

**Table 29. Average Generic Utilization**

Survey Year	Retail	Mail
2005	51%	39%
2004	47%	38%
2003	44%	34%
2002	42%	32%

**Table 30. Range of Generic Dispensing Rate in Retail and Mail-Service Pharmacies**

Point in Range	Percentage of Retail Pharmacy Prescriptions	Percentage of Mail Service Pharmacy Prescriptions
Lowest Percent Generic	33%	12%
Average Percent Generic	51%	39%
Highest Percent Generic	71%	65%

**Table 31. Impact of Copayment Difference on Retail Generic Dispensing**

Difference Between Tier 1 and Tier 3 Copays	Percentage of Retail Prescriptions Dispensed as Generic
\$0 \$24	46.3%
\$25 +	51.8%

**Table 32. Impact of Copayment Difference on Mail-Service Generic Dispensing**

Difference Between Tier 1 and Tier 3 Copays	Percentage of Mail Prescriptions Dispensed as Generic
\$0 \$65	38.8%
\$66 +	40.4%

Before the introduction of three-tier copayment schemes, the primary strategy to encourage generic utilization was to assess a financial penalty to beneficiaries who choose to accept a multi-source brand drug when a generic is available. Traditionally, this penalty was the difference in cost between the generic and brand drug. The intent was to keep the employer's cost the same whether the generic or brand was dispensed. With the introduction of a third copayment

tier and the assignment of multi-source brand drugs to that tier, some employers have chosen to eliminate the generic penalty. Financially, the third-tier copayment often approximates the amount that the patient would have paid with the penalty. More employers (55%) handle the multi-source brand situation with a higher copay than those who charge the difference in cost between the brand and the generic (41%).

## Marketplace Focus

### Medicare Part D Dominates Industry

Medicare Part D prescription drug coverage has brought a tsunami of activity to the drug benefit arena.

The health care industry—governmental programs, managed care organizations, insurance carriers, pharmacy benefit managers, employers, and union groups—is delivering drug benefits to 38 million Americans age 65 and over. As shown in Figure 13, more than 10 million Americans have creditable prescription drug coverage from employer-or union-sponsored plans. This includes drug benefit coverage provided through the Federal Employee Health Benefit Program and TRICARE. The segment of Medicare beneficiaries receiving drug benefits through Creditable Employer/ Union Coverage includes 6.9 million beneficiaries in Retiree Drug Subsidy (RDS) Plans.

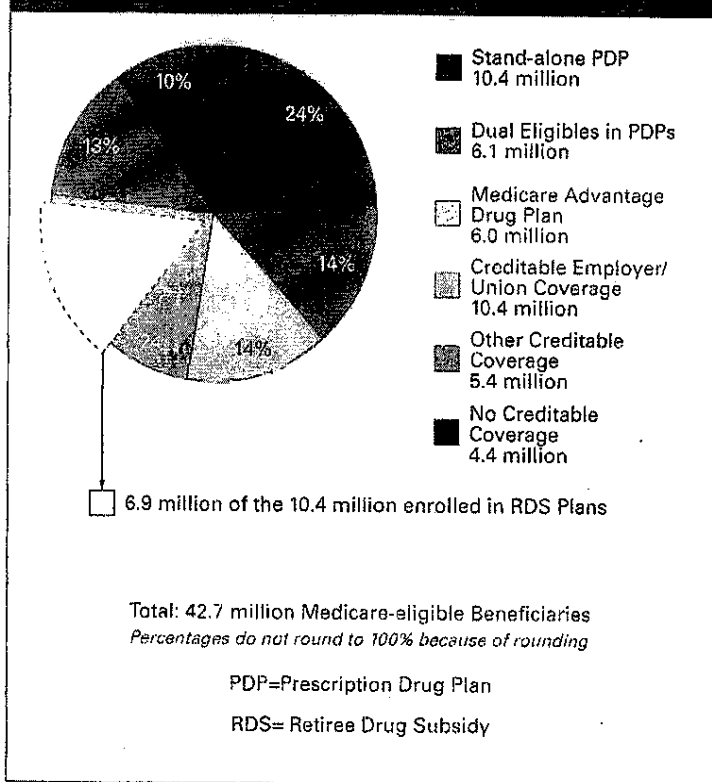
Employers and unions have partnered with their pharmacy benefit managers (PBMs), health plans, insurance carriers, and brokers to offer prescription drug coverage to 6.9 million in the form of plan designs actuarially equivalent to, or better than, the standard Medicare Part D drug benefit stipulated in the Medicare Modernization Act of 2003. Assuming they followed Centers for Medicare & Medicaid Services (CMS) protocols, these plan sponsors are eligible for the retiree drug subsidy (RDS). A PriceWaterhouseCoopers analysis<sup>1</sup> of Medicare beneficiaries estimates that there are another 2.5 million people enrolled in employer plans that are not part of the RDS program.

The majority of the Centers for Medicare & Medicaid Services (CMS) reports and related industry research studies about Part D address the 22.5 million beneficiaries receiving coverage through Stand-alone PDP, Medicare Advantage Drug Plan or as Dual Eligibles in PDPs. It's reasonable to assume that the experience of retirees receiving coverage through RDS plans is somewhat similar to the experience of the 22.5 million Part D enrollees.

#### Satisfaction with Benefit

More than eight in 10 seniors enrolled in a Medicare drug plan are satisfied with their plan, although almost two in 10 say they encountered a major problem in using it, according to a June 2006 Kaiser Family Foundation survey of seniors' experiences with Medicare Part D. The survey of 1,585 seniors, including 623 who are enrolled in a new Medicare Part D drug plan, shows that initial experiences under the drug benefit have been positive.

**Figure 13. HHS Estimates of Prescription Drug Coverage for Medicare Beneficiaries**



Source: HHS data for beneficiaries enrolled in creditable coverage programs released June 11, 2006.



Fewer people appear to be impacted by the donut hole benefit design than originally expected by industry analysts and consumer advocates. The donut hole is the gap in coverage between \$2,250 and \$3,600 in which beneficiaries must pay the cost of prescriptions. PriceWaterhouseCoopers' estimates that only 3.4 million or 8% of Medicare beneficiaries will have drug spending in the coverage gap. This is less than industry experts originally estimated.

### Marketplace Challenges

Information released from the Centers for Medicare & Medicaid Services (CMS) indicates that Part D enrollees may be experiencing some challenges getting their questions answered and using the benefit. CMS reports that the majority of beneficiary complaints involve the enrollment process, followed by issues surrounding drug availability, costs, and co-payments.

As this report went to press, employers were just beginning to receive RDS payments from CMS. There will be many months of analysis and administrative work to ensure payments match claims experience. The administrative complexity of managing Part D coverage for retirees is here to stay.

### Costs Indexed for 2007

Here are the 2007 benefit costs supplied by the Centers for Medicare & Medicaid Services (CMS). These numbers affect the design of a retiree benefit and the calculations involved in determining if a plan is actuarially equivalent to the Part D benefit provided by CMS.

**Deductible:** \$265

**Cost Sharing:** 75%/25% to \$2,400

**Out-of-pocket Maximum:** \$3,850

**Retiree Drug Subsidy Per Individual:**  
28% of covered Part D costs between \$265 and \$5,350

### Notes

<sup>1,2</sup>PriceWaterhouseCoopers. (2006). Significance of the Coverage Gap Under Medicare Part D. Accessed at [www.hlc.org/HLC\\_Coverage\\_Gap\\_Research\\_Report\\_FINAL.pdf](http://www.hlc.org/HLC_Coverage_Gap_Research_Report_FINAL.pdf).

### Online Resources

Visit the sites listed below for more information about Medicare Part D.

#### Beneficiary Information

[www.medicare.gov/medicarereform/drugbenefit.asp](http://www.medicare.gov/medicarereform/drugbenefit.asp)  
[www.medicaretoday.org](http://www.medicaretoday.org)

#### Centers for Medicare and Medicaid Services' Resources

General Employer/Union Overview: [www.cms.hhs.gov/EmplUnionPlanSponsorInfo/01\\_Overview.asp](http://www.cms.hhs.gov/EmplUnionPlanSponsorInfo/01_Overview.asp)  
Creditable Coverage: [www.cms.hhs.gov/CreditableCoverage/01\\_Overview.asp](http://www.cms.hhs.gov/CreditableCoverage/01_Overview.asp)  
Retiree Drug Subsidy: [www.cms.hhs.gov/EmployerRetireeDrugSubsid/01\\_Overview.asp](http://www.cms.hhs.gov/EmployerRetireeDrugSubsid/01_Overview.asp)  
Employer Group Waiver Plans: [www.cms.hhs.gov/EmpGrpWaivers/01\\_Overview.asp](http://www.cms.hhs.gov/EmpGrpWaivers/01_Overview.asp)

#### Foreign Language Assistance

Medicare Prescription Drug Plan selection, enrollment and application help in foreign languages.

##### Spanish Resources

National Alliance for Hispanic Health's Bilingual Su Familia [www.hispanichealth.org](http://www.hispanichealth.org)  
Toll-free telephone: 866-783 2645

##### Asian Resources

National Asian Pacific Center on Aging's National Multilingual Help Center [www.napca.org](http://www.napca.org)  
Toll-free telephone numbers: Chinese 1-800-582-4218 Korean 1-800-582-4259 Vietnamese 1-800-582-4336

### News Clippings

[www.gormanhealthgroup.com](http://www.gormanhealthgroup.com)  
[www.npcnow.org](http://www.npcnow.org)

### Research Studies and Resources

[www.kff.org/medicare/rxdrugs.cfm](http://www.kff.org/medicare/rxdrugs.cfm)

## Appendix: Supplemental Data

**Table 33. Retail Reimbursement by Industry Segment**

SIC	Brand Drugs			Generic Drugs
	Average AWP	Average Fee	Reimbursement Rate	Average Fee
Manufacturing	84.7%	\$1.85	86.2%	\$1.92
Transportation	84.4%	\$1.76	85.8%	\$1.81
Wholesale	84.6%	\$1.88	86.1%	\$1.97
Retail Trade	85.1%	\$1.84	86.6%	\$1.95
Finance	84.6%	\$1.82	86.1%	\$1.94
Services	84.6%	\$1.92	86.2%	\$2.03
Public Admin.	84.5%	\$1.80	85.9%	\$1.86
All Others	85.0%	\$2.09	86.7%	\$2.16
Total	84.7%	\$1.88	86.2%	\$1.97

**Table 34. Mail Reimbursement by Geographic Location**

Region	Brand Drugs			Generic Drugs
	Average AWP	Average Fee	Reimbursement Rate	Average Fee
Northeast	77.8%	\$0.17	77.9%	\$0.20
South	78.3%	\$0.25	78.4%	\$0.28
Midwest	77.9%	\$0.24	77.9%	\$0.28
West	78.8%	\$0.38	78.9%	\$0.36
All	78.1%	\$0.24	78.1%	\$0.26

**Table 35. Mail Reimbursement Rate by Industry Segment**

SIC	Brand Drugs			Generic Drugs
	Average AWP	Average Fee	Reimbursement Rate	Average Fee
Manufacturing	77.9%	\$0.19	78.0%	\$0.20
Transportation	77.5%	\$0.16	77.5%	\$0.25
Wholesale	78.1%	\$0.24	78.2%	\$0.24
Retail Trade	79.3%	\$0.25	79.4%	\$0.25
Finance	78.3%	\$0.23	78.3%	\$0.21
Services	78.0%	\$0.30	78.0%	\$0.36
Public Admin.	77.9%	\$0.15	77.9%	\$0.16
All Others	78.8%	\$0.27	78.9%	\$0.27
Total	78.1%	\$0.24	78.1%	\$0.26



<b>Table 36. Retail Cost Sharing by Industry Segment</b>				
SIC	Average Copayments			% With Coinsurance
	First Tier	Second Tier	Third Tier	
Manufacturing	\$9.35	\$19.82	\$36.52	41%
Transportation	\$9.42	\$19.13	\$33.33	50%
Wholesale	\$9.00	\$21.69	\$33.00	24%
Retail Trade	\$10.39	\$23.22	\$42.64	53%
Finance	\$9.31	\$21.84	\$40.54	25%
Services	\$9.06	\$20.39	\$38.21	32%
Public Admin.	\$8.42	\$19.31	\$36.04	20%
All Others	\$11.28	\$22.03	\$42.95	39%
Total	\$9.53	\$21.61	\$39.06	35%

<b>Table 37. Mail-Service Cost Sharing by Industry Segment</b>				
SIC	Average Copayments			% With Coinsurance
	First Tier	Second Tier	Third Tier	
Manufacturing	\$18.05	\$40.46	\$73.76	27%
Transportation	\$16.96	\$35.91	\$65.50	32%
Wholesale	\$18.29	\$41.33	\$67.05	13%
Retail Trade	\$20.09	\$47.47	\$86.91	30%
Finance	\$18.97	\$44.72	\$85.17	18%
Services	\$16.82	\$40.44	\$75.31	19%
Public Admin.	\$14.96	\$34.96	\$64.31	20%
All Others	\$21.33	\$42.93	\$82.62	24%
Total	\$17.95	\$41.65	\$77.05	23%

<b>Table 38. Mail-Service Cost Sharing by Geographic Location</b>				
Region	Average Copayments			% With Coinsurance
	First Tier	Second Tier	Third Tier	
Northeast	\$16.41	\$37.31	\$71.68	14%
South	\$18.75	\$45.74	\$82.30	18%
Midwest	\$18.09	\$40.08	\$72.84	29%
West	\$15.00	\$35.94	\$70.47	33%
All	\$17.95	\$41.65	\$77.05	23%

**Table 39. Percentage of Respondents by Whether Plan Is Negotiated**

Plan Description	Percentage of Respondents
Negotiated Benefit (Union/Trust)	20%
Not Negotiated	79%
Don't Know	1%

**Table 40. Percentage of Respondents With Specialty Pharmacy**

Specialty Pharmacy Offering	Percentage of Respondents
Offer Specialty Pharmacy	59%
Do Not Offer Specialty Pharmacy	41%

**Table 41. Percentage of Respondents Who Fill Maintenance Medications at Retail Pharmacies**

Plan Design for Maintenance Medications	Percentage of Respondents
Allow 60+ Days Retail Maintenance	28%
Do Not Allow 60+ Days Retail Maintenance	72%

**Table 42. Percentage of Respondents With Transparent PBM Financial Relationship**

Perception of PBM Financial Relationship	Percentage of Respondents
Transparent	52%
Not Transparent	48%

TAK-00015 9/06

**CREATING OPPORTUNITIES WITH HEALTHCARE SOLUTIONS**

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# **Exhibit 21A**

1 UNITED STATES DISTRICT COURT  
2 FOR THE DISTRICT OF MASSACHUSETTS  
3

 ORIGINAL

--O--

4  
5 NEW ENGLAND CARPENTERS HEALTH : Civil Action No.:  
BENEFITS FUND, ET AL., 1:05-CV011148-PBS

6 :  
Plaintiffs,

7 :  
-v-

8 :  
FIRST DATABANK, INC., and

9 McKESSON CORPORATION, : Deposition of:  
H. ERIC CANNON

10 Defendants, :  
11

12 --O--  
13

14 Place TEMPEST REPORTING, INC.  
15 230 South 500 East  
16 Suite 530  
17 Salt Lake City, Utah 84102  
18

19 Date: October 11, 2006  
20 9 55 a m.  
21

22 Reporter: Ariel Mumma, CSR/RPR  
23  
24

25 --O--

1 A. My initial employment was pharmacy  
2 utilization coordinator.

3 Q. When was that?

4 A. 1997 through -- and I'm foggy on this --  
5 so '98 to '99; '99 to 2000 it was manager of pharmacy  
6 services

7 Q. And then were you manager of pharmacy  
8 services up until the point when you became director  
9 of pharmacy services?

10 A. Yes.

11 Q. What are your responsibilities as director  
12 of pharmacy services?

13 A. I oversee all utilization of  
14 pharmaceuticals for the membership of SelectHealth.  
15 That would include responsibility for contracting with  
16 network pharmacies, any PBM arrangements, mail-order  
17 pharmacy arrangements, contracting with drug  
18 manufacturers, utilization management, medical  
19 expense. If it has to do with pharmaceuticals, it is  
20 my responsibility.

21 Q. Is it important to keep up to date on  
22 prescription drug pricing issues in your position as  
23 director of pharmacy services?

24 A. It -- yes.

25 Q. What types of things do you do to keep up

1 to date?

2 A. We track national trends; we track our own  
3 internal trends; we track utilization mix; we track  
4 inflation values for particular products, particular  
5 drug classes.

6 We look at contracting trends across the  
7 country, and from that I mean our people contracting  
8 on an AWP-minus basis, what types of dispensing fees  
9 do they use.

10 We track -- we've been tracking the recent  
11 changes with the federal government in reimbursement  
12 of injectable drugs as it relates to ASP pricing; we  
13 track, to a lesser degree, trends related to WAC, and  
14 that's simply because our payment methodologies are  
15 based off of AWP.

16 We do collect rebates on some items based  
17 on WAC, but we do not track that very closely.

18 Q. How do you track national trends?

19 A. National trend reports. The Novartis  
20 trend report. Express Groups has a trend report.  
21 Medco has a trend report.

22 We participate in some national surveys.

23 Health Strategies out of San Francisco I  
24 think is one that we've participated in, they supply  
25 us with the work product when that is done.

1 easier to implement within their populations.

2 Q. Do you think the variety of different  
3 types of programs that any one employer is using has  
4 increased; in other words, they may have just had a  
5 co-pay -- tiered co-pay program five years ago, but  
6 now they have a tiered co-pay program, and a  
7 step-therapy program, and a generic substitution  
8 program?

9 A. Yes.

10 Q. So the variety in the types of cost-saving  
11 measures that employers have been using has increased  
12 over time?

13 A. Yes.

14 Q. Are you familiar with the term "average  
15 wholesale price," AWP?

16 A. Yes.

17 Q. What do you understand it to mean?

18 A. Average wholesale price, as I understand  
19 it, is a price that is set, either by the distributor  
20 of data, First DataBank, Medi-Span, or the supplier of  
21 the product, the pharmaceutical company; and I say  
22 that in that I don't fully understand in my role where  
23 that price is set, and over the years I've asked the  
24 question of mainly manufacturers, and received  
25 different answers.



Reporter's Certificate

State of Utah )  
County of Salt Lake )

I, Ariel Mumma, Certified Shorthand  
Reporter, Registered Professional Reporter, and Notary  
Public for the State of Utah, do hereby certify:

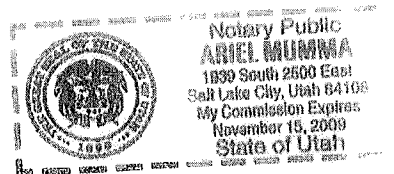
THAT the foregoing proceedings were taken  
before me at the time and place set forth herein; that  
the witness was duly sworn to tell the truth, the  
whole truth, and nothing but the truth; and that the  
proceedings were taken down by me in shorthand and  
thereafter transcribed into typewriting under my  
direction and supervision;

THAT the foregoing pages contain a true  
and correct transcription of my said shorthand notes  
so taken

IN WITNESS WHEREOF, I have subscribed my  
name and affixed my seal this 17<sup>th</sup> day of  
October, 2006.

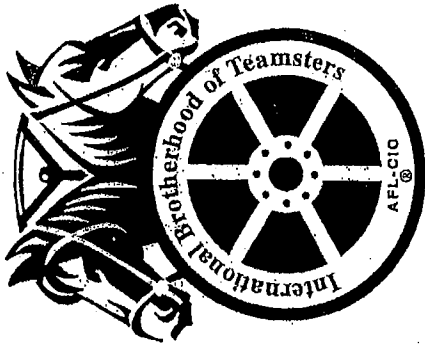
*Ariel Mumma*  
Notary Public

My commission expires  
November 15, 2009.



# **Exhibit 22C**

THWF0001



# SUMMARY PLAN DESCRIPTION

of the

Plan of Benefits

of the

TEAMSTERS HEALTH  
AND WELFARE FUND

*of Philadelphia and Vicinity*

JANUARY, 2001



Teamsters Health & Welfare Fund of  
Philadelphia and Vicinity  
Fourth & Cherry Streets  
Philadelphia, PA 19106

## NOTES

This Booklet and the accompanying Summary of Benefits Schedule constitute the Fund's Plan document. This Booklet contains the Fund's complete Health and Welfare Benefit program as of the date of publication. The only benefits to which you are entitled are those stated in this booklet and in the Summary of Benefits Schedule which accompanies this booklet, and are determined by the rate of contribution as defined in the Collective Bargaining Agreement between your Employer and Union.

**Please note:** For those participants enrolled in either the *Personal Choice™* or *Keystone HMO™* plans, your hospital and medical/ surgical benefits are those set forth in the Member Handbook sent to you by Independence Blue Cross. The content of those booklets is incorporated in this document by reference. For those enrolled in those programs, please consult those booklets for an explanation of your benefit coverage. However, no matter which medical program you choose for you and your eligible dependents (Traditional, *Personal Choice™* or *Keystone HMO™*) certain benefits are common to all programs – dental, vision, weekly disability, death, and prescription drug benefits. These benefits are described in this booklet and in the Summary of Benefits Schedule.

From time to time, the Fund's Trustees may amend your Plan of Benefits. Should that occur, the Fund routinely advises you of such changes in the Fund's newsletter or by way of special bulletins.

*The only person authorized to advise you of your rights under this Plan is the Fund Administrator, William J. Einhorn, or his specific designee.*

*Reliance upon information from any other source is at your own risk.*

THWF0002

THWF0003

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13. Q. Can I get contact lenses instead of glasses?

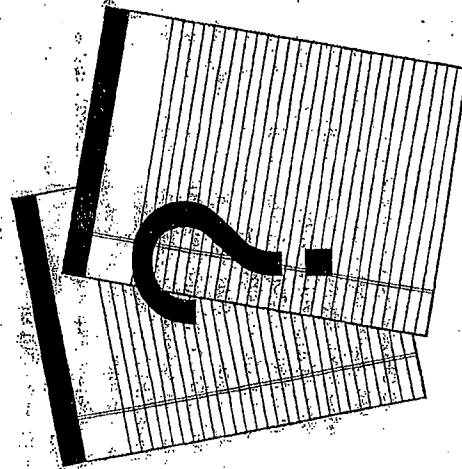
A. Yes. However, contact lenses are reimbursed by combining the allowances for frames and single vision lenses.

14. Q. My physician prescribed a medication, but my pharmacist said it wasn't covered under my Plan. Why isn't it covered?

A. Although the vast majority of prescription drugs are covered under the Prescription Drug Program, some drugs, such as vitamins, birth control pills, drugs for weight reduction, drugs prescribed for cosmetic purposes, experimental and/or investigational drugs (or drugs that are not experimental and/or investigational, but are used for an experimental and/or investigational purpose), are not covered.

15. Q. Well, I feel that I understand my coverage much better now, but if I have any other questions, may I contact the Fund Office?

A. Yes, please do; but please keep this Booklet and the Summary of Benefits Schedule handy for future reference. Incidentally, should you find it necessary to call the Fund, it is very helpful if you can provide us with the member's social security number, the name of the provider of service and the date the service was performed.



**BOARD OF TRUSTEES****LABOR TRUSTEES**

Paul Cardullo, President  
I.B.T. Local 929  
4345 Frankford Avenue  
Philadelphia, PA 19124

Thomas P. Hummel, President  
I.B.T. Local 470  
3565 Sepviva Street  
Philadelphia, PA 19134

William Hamilton, Jr., President  
I.B.T. Local 107  
107 Spring Garden Street  
Philadelphia, PA 19123

**MANAGEMENT TRUSTEES**

Arnold S. Rosenthal  
9752 Morefield Road  
Philadelphia, PA 19115

Kenneth F. Leedy, President/CEO  
New Penn Motor Express  
625 South Fifth Avenue  
Lebanon, PA 17042

Bob Schaeffer, Executive Director  
Transport Employers Association  
56 Main Street,  
Second Floor  
Camillus, NY 13031

**FUND ADMINISTRATOR AND AGENT FOR SERVICE OF LEGAL PROCESS**

(Legal process may also be served upon a Trustee)

William J. Einhorn, Administrator  
Fourth & Cherry Streets  
Philadelphia, PA 19106

**LEGAL COUNSEL**

Schnader, Harrison  
Segal & Lewis, LLP  
Suite 3600, 1600 Market Street  
Philadelphia, PA 19103

**AUDITOR**

Ernst & Young, LLP  
Two Commerce Square, Suite 400  
Philadelphia, PA 19103

**INVESTMENT MANAGER**

SEI Investments  
One Freedom Valley Drive  
Oaks, PA 19456

**DENTAL PROGRAM CONSULTANT**

Louis P. Mattucci & Associates  
1037 Mill Creek Drive, Suite A-1  
Feasterville, PA 19053

**PRESCRIPTION DRUG PROGRAM**

General Prescription Programs, Inc.  
127 East 59th Street  
New York, NY 10022

**PHARMACY UTILIZATION REVIEW**

Pharmaceutical Care Network  
9343 Tech Center Drive, Suite 200  
Sacramento, CA 95826

**HOSPITAL CLAIMS****ADMINISTRATION SERVICE**

The Fund has entered into an  
Administrative Services  
arrangement with the following and its  
subsidiaries:  
Independence Blue Cross  
1901 Market Street  
Philadelphia, PA 19103-1480

Among other employees, the Health &  
Welfare Fund covers employees  
represented by these Teamsters Locals

Local 107 Local 384  
Local 115 Local 470  
Local 169 Local 500  
Local 312 Local 623  
Local 326 Local 628  
Local 331 Local 676  
Local 929

Summary of Benefits Schedule to determine what this maximum is), the Fund will begin to pay a large percentage of all Covered Expenses.

10. Q. What is the Fund's position on cosmetic surgery?

A. Generally speaking the Fund does not cover cosmetic surgery. When in doubt as to whether a particular surgery is considered cosmetic or not, contact the Fund prior to incurring any out-of-pocket expenses for which the Fund will not reimburse you.

11. Q. My wife and I just had a baby; when is our child eligible for coverage under this Plan?

A. With the exception for the Death Benefit, which differs depending on the age of the child, your child is eligible immediately for the first 31 days of the child's life, assuming of course, that you are eligible and you participate in one of the Fund's benefit programs that has dependent coverage. However, for coverage to continue beyond this 31 day period, it is most important that you notify the Fund of this new Family Member as soon as possible by filling out and returning to the Fund a new Census Card. You must also send the Fund a copy of the child's birth certificate.

12. Q. I went to a PPO provider and now I'm getting a bill. Why?

A. If you went to a PPO provider for dental or vision benefits, this could happen for several reasons. In the case of a dental claim, you could receive a bill if you have already reached the yearly or lifetime dental maximum benefit for that patient, or you received services sooner than allowed, or you received non-covered services. Under the vision program, you may be billed the additional fees for non-covered items, such as designer frames, sunglass- es, transitional lenses and invisible (or progressive) bifocal lenses. *Remember: Although the Fund strives to keep the provider directories current (they are updated approximately every two months), check with the Fund office or the provider to make sure the provider is still participating in the PPO panel.* In some cases, you will receive a bill from the provider for a major medical claim. You could be billed for non-covered items, your deductible, your copayment, or for charges which exceeded plan maximums.

THWF0005

**TEAMSTERS HEALTH AND WELFARE FUND OF  
PHILADELPHIA AND VICINITY**

Fourth and Cherry Streets  
Philadelphia, Pennsylvania 19106  
(215) 923-6300 (800) 523-2846

January 2001

Dear Member:

Several years have passed since our last Benefit Booklet was published. In the intervening years, many amendments to the Plan and new types of benefit programs have been adopted by your Board of Trustees. Every effort has been made to keep you abreast of these changes either through special bulletins or notices in the Fund's newsletter, *Philadelphia Update*, which is published several times each year.

New and innovative programs have been implemented by the Fund in recent years. The "Triple Option" medical program, the Dental PPO, Vision PPO and Outpatient X-Ray PPO Programs have served as models upon which other benefit plans have relied and copied. The Fund's service agreement with Independence Blue Cross has given members what they have wanted for the longest time - a permanent identification card, good anywhere in the country - and at the same time, has streamlined hospital claim processing with significant savings to the Fund.

You can help conserve your valuable benefits by:

- Discussing fees with your physician. He estimates what he thinks you can pay. If you do not act concerned, he may overestimate.
- Requesting outpatient hospital care whenever possible.
- Questioning what appears to be unnecessary hospital treatment or charges as you would if you were paying the bill.
- Requesting that your physician not keep you in the hospital for any longer than necessary.
- Requesting pre-admission testing (see Hospital Expense Benefits).
- Obtaining a second opinion on non-emergency surgery (see Surgical Expense Benefits).
- Following the Fund's Pre-Admission Certification rules (see page 26).

Take the time to read the material in this booklet. These are valuable benefits that are of critical importance to you and your family. Every effort has been made to describe your benefit coverage in easy-to-understand language. Nevertheless, health coverage is a complicated item that oftentimes does not lend itself to easily described terms and concepts. For that reason, the Fund maintains a Member Services Department staffed with highly trained personnel, well versed in the Fund's plans, and ready to answer your questions and benefit inquiries.

We hope you will agree that these are valuable benefits to be used wisely. Get the most value for each of your Fund dollars by being an *aware, informed and concerned* health benefits consumer.

Sincerely,

**THE BOARD OF TRUSTEES**

Paul Cardullo, Local 929 (Union Co-Chairman) Arnold S. Rosenthal (Employer Co-Chairman)  
Thomas P. Hummel, Local 470 Kenneth F. Leedy, New Penn Motor Express  
William Hamilton, Jr., Local 107 Bob Schaeffer, Jr., Transport Employers Assoc.

1

2. Workmen's Compensation Benefits are far more valuable than those under the Fund, and

3. Should you first file your claim with the Fund and the Fund subsequently denies payment because it is job related, the delay thus caused could affect receipt of benefits under Workmen's Compensation.

4. On the other hand, should you file with Workmen's Compensation first, and be denied by Referee decision, upon presentation of the Referee denial from Workmen's Compensation to the Fund, your claim will be honored unless, of course, your denial was for procedural reasons and not because the findings were that the illness or injury was not job related.

7. Q. Exactly what does the Major Medical deductible mean?

A. It is similar to the deductible you have with your car insurance. Prior to any benefits being paid under your Major Medical Plan, you must first pay a deductible amount out of your own pocket. This amount is shown in the Summary of Benefits Schedule. Once you satisfy this out-of-pocket deductible the Fund pays a large percentage of any Covered Expenses. Beyond this, you will continue to pay a small portion of your Major Medical expenses until you satisfy your co-payment amount as indicated in the Summary of Benefits Schedule Insert. At that point the Fund will generally be covering 100% of your Major Medical expenses, subject to the Plan maximums and limitations.

8. Q. If I go to the doctor about two times a month for treatment, can I claim this expense under my Major Medical Plan?

A. Yes. If you have office visits, clinic visits or consultations, these are all covered under your Major Medical Plan. While no benefits will be paid until you satisfy your deductible, as long as the claims are submitted, the charge will be credited towards your deductible and once this is satisfied, the balance of your claims will be paid at the appropriate percentage.

9. Q. I have myself, my wife and four children and sometimes our medical bills are too much. Do each of us have to satisfy the deductible?

A. Yes, but there is also a family clause in the Plan. If the family as a whole has reached the family deductible maximum (see your



## ELIGIBILITY PROVISIONS

### ELIGIBILITY

A member of the Teamsters Health and Welfare Fund of Philadelphia and Vicinity will become and remain eligible for the Benefits Program in accordance with the "Qualifying Schedule" shown in the eligibility provisions of the Summary of Benefits Schedule. It is important to consult that schedule because, depending upon the terms of the collective bargaining agreement between your Local Union and your Employer, there are different methods of determining when you become eligible for benefits and when you lose eligibility for those benefits.

A Family Member means, in addition to yourself, any one of your eligible dependents who is covered under this Plan as defined below under "Dependents." Benefits for each of your covered dependents will be determined on the same basis as for you except where noted.

### DEPENDENTS

- a. Your spouse (as defined herein), provided you are not separated.
- b. Your unmarried children (including any stepchildren, adopted children or children living with you for whom you are appointed legal guardian by a court and for whom you are financially responsible) until their 19th birthday.

Dependent children will be covered for benefits up to their 23rd birthday or date of graduation (whichever occurs first) if they are enrolled as full-time students at an accredited educational institution. Proof of attendance as a full-time student must be submitted to the Fund each semester.

Any individual who is a full-time member of the Armed Forces or who is eligible for coverage as an Employee under this or any other employer-sponsored plan is not eligible to be a Dependent under this Plan.

- c. Your wholly dependent, unmarried children who are physically or mentally incapable of self-support upon attaining age nineteen (19) will continue to be covered ONLY under your BASIC coverage providing you furnish the Fund Office with proof of this incapacity before their coverage terminates at age nineteen (19). You should request the appropriate form from the Fund Office.

## QUESTIONS AND ANSWERS

1. Q. To whom are benefits payable?

A. Your Death Benefit is payable to your beneficiary of record. Other benefits are payable to you, the member, although you may assign your benefits to the physician or hospital.

2. Q. Will the Fund automatically accept my physician's signed statement on my claim form?

A. Not always. The Fund reserves the right to ask for a medical examination by its own appointed physician.

3. Q. May I select my own physician?

A. Yes, as long as he is licensed to practice in accordance with all applicable laws. Remember, however, you may have certain restrictions if you are covered under the *Keystone HMO™* program. Also keep in mind that, under the *Personal Choice™* program, higher deductibles and copayments apply if the doctor you select is not in the *Personal Choice™* network.

4. Q. May I go to any hospital or am I limited to certain ones?

A. Benefits are payable to any hospital which meets the definitions of hospital contained in this Booklet. But please remember to comply with the Fund's Pre-Admission Certification rules. For those enrolled in either the *Personal Choice™* or *Keystone HMO™* programs, be sure to consult your Provider Directory.

5. Q. Can I collect Weekly Disability Benefits and unemployment compensation at the same time?

A. No, collection of unemployment compensation shall be evidence that a member is able and available for suitable work and, therefore, would not be entitled to Weekly Disability Benefits.

6. Q. If my disability arose during the course of my employment, would it be all right for me to submit a claim to the Fund?

A. A claim for a disability that originates in the course of employment should be filed with Workmen's Compensation, because:

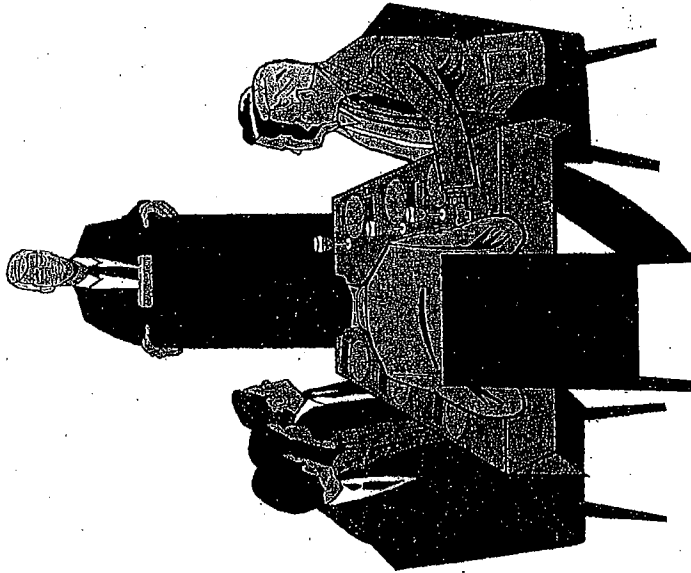
1. Charges for treatment of work related injuries are not covered under the Plan, and

THWF0006



either of the parties. The arbitrator shall have the authority to assess such fees and expenses against the Fund if the appealing party's claim is not frivolous. The decision of the arbitrator shall be final and binding upon the Trustees and upon the appealing party.

The procedures specified in this section shall be the sole and exclusive procedures available to the Family Member who is dissatisfied with an eligibility determination, or benefit award, or who is otherwise adversely affected by any action of the Trustees.

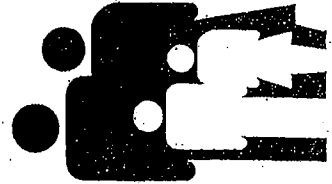


- d. Your wholly dependent parents, providing you are unmarried and have no other dependents and such parents are living in your household. Major Medical coverage will not be provided for parents who are eligible to apply for benefits under any medical assistance program for the aged provided by a State or the Federal Government.

**NOTE:** When both a husband and wife are covered by the Fund as eligible members, Plan deductibles and co-payments will not be taken. Beyond that, payment will be determined based upon Fund allowances (UCR, etc.) and under Coordination of Benefits (see General Provisions and Definitions section).

#### ***Change in Family Status:***

It is important that you give prompt, written, notice to the Fund Office on the Census Card found in this Booklet of any change in your Family Members, such as marriage, birth of a child, death of your spouse, divorce, or separation. Furthermore, a description of the procedures governing qualified medical child support order determinations can be obtained, without charge, from the Fund Office. Failure to report any change in your Family Members may result in a delay of payment of a claim at a future date or may adversely affect your COBRA right to continued coverage. Census Cards are always available at the Fund Office. In certain situations you may be required to submit a certified copy of your most recent federal income tax return and other necessary documents in order to establish proof of dependency for a particular Family Member. Similarly, it is most important that you immediately notify the Fund of any change in your address.



THWF0007

## TERMINATION OF COVERAGE PROVISIONS

### LOSS OF MEMBER ELIGIBILITY

A member's eligibility shall automatically terminate if any of the following take place:

- a. When a member has less than the required number of days' contributions to his credit in accordance with the Qualifying Schedule of Eligibility set forth in the Summary of Benefits Schedule and does not qualify for the Extension of Benefits Provisions on the following page; or
- b. When a member ceases to be a member of a class of employees covered by his employer's Collective Bargaining Agreement with a participating Local Union, or otherwise no longer qualifies as a Member as defined herein, (except that if the employee retires, eligibility will continue in accordance with the "Qualifying Schedule" in the Summary of Benefits Schedule, and further, if a member leaves Covered Employment prior to retirement, he or she may continue to exhaust earned eligibility credits for a period not to exceed two (2) months); or
- c. When a member becomes self-employed outside the scope of a Collective Bargaining Agreement; or
- d. When a member enters full-time military, naval or air service; or
- e. When the benefit program is terminated; or

- f. Immediately upon the date on which any Participating Local Union and Contributing Employer(s) agree that the then Contributing Employer(s) shall no longer make contributions to the Fund.

**NOTE:** No matter what else might be written in this Booklet, a member shall not be eligible for benefits incurred during any Benefit period in which:

1. His employer is not a Contributing Employer, or
2. His employer is making contributions or payments of any kind to any party (other than this Fund) for the purpose of providing Health and Welfare benefits which duplicate in any way the benefits provided under this Fund.

- d. The Review Committee will issue a decision not later than sixty (60) days after it receives your request for a review (or within sixty (60) days after all necessary information is received by the Committee), reaffirming, modifying or setting aside the former action.

- e. Review by a Hearing Panel of the Board of Trustees:

Any Family Member who has had his claim denied by the Claims Review Committee shall have the right to request the Board of Trustees to designate a Hearing Panel (to be composed of at least two (2) Trustees) to conduct a hearing in the matter, provided that he makes such a request, in writing within sixty (60) days after becoming apprised of, or learning of, the Claims Review Committee's action.

The Hearing Panel shall then conduct a hearing, at which the Family Member shall be entitled to present his position and any evidence in support thereof. The Family Member may be represented at any such hearing by an attorney or by any other representative of his choosing. Thereafter, the Trustees shall issue a written decision reaffirming, modifying or setting aside their former action.

In exercising their duties, the Trustees, the Administrator or any person properly exercising authority delegated by the Trustees or Administrator, shall have the fullest degree of discretion allowed by law in determining eligibility for benefits and in construing the terms of this Plan and related documents.

- f. Review by an impartial arbitrator:

If the Family Member is dissatisfied with the written decision of the Trustees, he shall have the right to appeal the matter to arbitration in accordance with the Voluntary Labor Arbitration Rules of the American Arbitration Association, provided that he submitted a request for arbitration to the Board of Trustees, in writing, within sixty (60) days of receipt of the Trustees' written decision.

The question for the arbitrator shall be whether in the particular instance, the Trustees (1) were in error upon an issue of law, (2) acted arbitrarily or capriciously in the exercise of their discretion or (3) whether their findings of fact were supported by substantial evidence.

The administration fees of the American Arbitration Association shall be borne equally by the appealing party, and by the Trust Fund, and the arbitrator's fee and expenses shall also be borne equally, unless the arbitrator, in his award, should assess such expenses against

### CLAIM REVIEW / CLAIM APPEAL PROCEDURE HERE IS YOUR PROCEDURE FOR HAVING A CLAIM REVIEWED

a. If your claim is denied or partly denied, you will be notified in writing and given an opportunity for a review. If your claim is not acted on within a reasonable time, you may proceed to the review procedure stage, described below, as if the claim had been denied. You or your representative may review any documents relating to the denial and submit comments, in writing, to the Fund.

b. The written denial will give:

1. The specific reason(s) for denial.
2. A reference to the specific Plan provision(s) on which the denial is based.
3. A description of any additional material or information necessary to perfect the claim and the reason why such material or information is needed.
4. An explanation of the Plan's claim review procedure.

c. Claim review procedure:

1. Where a claim has been denied or partly denied, you may appeal the denial and have a review. Your written request should contain the following:

- a. Your name, address and social security number.
- b. The claim number, if one appears on the notice of rejection.
- c. The name of the patient, and the relationship to the member.
- d. The date of service for which the claim was made.
- e. A statement of the reason(s) you believe the claim rejection is in error.

2. Within ninety (90) days after you receive written notice that your claim has been denied, you or your representative may make a written request for review to the Review Committee.

### LOSS OF DEPENDENT ELIGIBILITY

A dependent's eligibility shall automatically terminate if any of the following take place:

- a. When the member's eligibility terminates; or
- b. When a dependent becomes an employee of any Employer and earns enough income to lose dependency status under the Internal Revenue Code; or
- c. When a dependent enters full-time military, naval or air service; or
- d. When a dependent ceases to be a "dependent" as defined herein; or
- e. In the case of children:
  1. When you can no longer claim your child as a dependent on your Federal Income Tax Return; or
  2. When a member's child(ren) attain the age of 19 years (or 23 if attending an accredited school or college on a full-time basis), except children who are physically or mentally incapable of self-support (see page 4, item c); or
  3. When a dependent child is married; or
  4. When a dependent child becomes eligible as an employee under a group health plan sponsored by any employer.



### Enforce Your Rights

If your claim for a welfare benefit is denied or ignored, in whole or in part, you have a right to know why this was done, to obtain copies of documents relating to the decision without charge, and to appeal any denial, all within certain time schedules.

Under ERISA, there are steps you can take to enforce the above rights. For instance, if you request a copy of plan documents or the latest annual report from the plan and do not receive them within 30 days, you may file suit in a Federal court. In such a case, the court may require the plan administrator to provide the materials and pay you up to \$110 a day until you receive the materials, unless the materials were not sent because of reasons beyond the control of the administrator. If you have a claim for benefits which is denied or ignored, in whole or in part, you may file suit in a state or Federal court. In addition, if you disagree with the plan's decision or lack thereof concerning the qualified status of a domestic relations order or a medical child support order, you may file suit in Federal court. If it should happen that plan fiduciaries misuse the plan's money, or if you are discriminated against for asserting your rights, you may seek assistance from the U.S. Department of Labor, or you may file suit in a Federal court. The court will decide who should pay court costs and legal fees. If you are successful the court may order the person you have sued to pay these costs and fees. If you lose, the court may order you to pay these costs and fees, for example, if it finds your claim is frivolous.

### Assistance with Your Questions

If you have any questions about your plan, you should contact the plan administrator. If you have any questions about this statement or about your rights under ERISA, or if you need assistance in obtaining documents from the plan administrator, you should contact the nearest office of the Pension and Welfare Benefits Administration, U.S. Department of Labor, listed in your telephone directory or the Division of Technical Assistance and Inquiries, Pension and Welfare Benefits Administration, U.S. Department of Labor, 200 Constitution Avenue N.W., Washington, D.C. 20210. You may also obtain certain publications about your rights and responsibilities under ERISA by calling the publications hotline of the Pension and Welfare Benefits Administration.

### EXTENSION OF BENEFITS

Should the member lose eligibility because he has less than the required number of contribution days to his credit as set forth in the Qualifying Schedule of Eligibility, then Covered Expenses incurred after a Family Member is no longer eligible for the Benefit Program will be considered Covered Expenses payable under this Plan provided the following conditions are satisfied:

#### FOR BASIC AND MAJOR MEDICAL BENEFITS

##### (90 Days Extended Care)

A medical claim will be considered related to a previous eligible claim and have all Basic and Major Medical Benefits continued (not treated as a new claim) provided:

1. The current actual charges are related to a diagnosis which was initially treated while the patient was eligible for benefits, and
2. The current actual charges were incurred within ninety (90) days of the initial treatment (that is, first date of service by a medical service provider) of the related injury or disease.

#### FOR MAJOR MEDICAL BENEFITS

##### (Extended Major Medical) (Traditional Plan Only)

Medical claims will be payable under this provision provided:

1. They are incurred prior to the end of a one year period immediately following the date the Family Member became ineligible for the Benefit Program; and
2. They are for an illness or injury incurred while the Family Member was eligible and which has rendered the Family Member Totally Disabled from the date the Family Member first became ineligible until the date the covered expense was incurred; and
3. The Family Member has not become protected under any other plan providing medical benefits; and
4. They are not covered under the 90 Day Extended Care provision.

### IMPORTANT NOTE

Before Extended Major Medical Benefits may be granted, it is necessary that a special form be filed with the Fund. You can request this form from the Fund Office and it must be completed by both the patient and the patient's treating physician in order to verify the patient's total disability.

THWF0010

## COBRA CONTINUATION COVERAGE

In some cases, should you and/or your dependents become ineligible for coverage under the Fund's Plan of Benefits, you have certain rights, under certain conditions, to continue your coverage under a federal law known as the Consolidated Omnibus Budget Reconciliation Act of 1985 ("COBRA").

Under this law, there are circumstances under which you can receive a temporary extension of your health care coverage at group rates. This extension applies to you and your dependents if you and they were covered by the Fund on the day before your or their coverage ended. COBRA refers to these people as "Qualified Beneficiaries."

A Qualified Beneficiary need not show evidence of good health in order to continue coverage. However, the Qualified Beneficiary is obligated to pay a set amount as a premium for this continuation of coverage. The premium that must be paid may be different than the contribution rate being paid by your employer. The COBRA premium rates are formulated by the Fund's Actuary in accordance with formulas defined in the federal COBRA law. Pro rated credits are given in those cases where the Employer has made some contributions on your behalf, but not enough for you to qualify for normal eligibility.

A member has the right to extend his coverage if the coverage ends because:

- a. You leave employment with an employer for reasons other than gross misconduct on your part; or
- b. You no longer meet the eligibility requirements.

Your spouse has the right to extend coverage if:

- a. You die;
- b. You leave employment as described above, or no longer meet the eligibility requirements;
- c. You are divorced or separated; or
- d. You become eligible for Medicare.

Your dependent children have the right to this extended coverage if:

- a. You die;
- b. You leave employment as described above, or no longer meet the eligibility requirements;
- c. You are divorced or separated;

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filled by the plan with the U.S. Department of Labor and available at the Public Disclosure Room of the Pension and Welfare Benefit Administration.

Obtain, upon written request to the plan administrator, copies of documents governing the operation of the plan, including insurance contracts and collective bargaining agreements, and copies of the latest annual report (Form 5500 Series) and updated summary plan description. The administrator may make a reasonable charge for the copies.

Receive a summary of the plan's annual financial report. The plan administrator is required by law to furnish each participant with a copy of this summary annual report.

### Continue Group Health Plan Coverage

Continue health care coverage for yourself, spouse or dependents if there is a loss of coverage under the plan as a result of a qualifying event. You or your dependents may have to pay for such coverage. Review this summary plan description and the documents governing the plan on the rules governing your COBRA continuation coverage rights.

Reduction or elimination of exclusionary periods of coverage for preexisting conditions under your group health plan, if you have creditable coverage from another plan. You should be provided a certificate of creditable coverage, free of charge, from your group health plan or health insurance issuer when you lose coverage under the plan, when you become entitled to elect COBRA continuation coverage, when your COBRA continuation coverage ceases, if you request it before losing coverage, or if you request it up to 24 months after losing coverage. Without evidence of creditable coverage, you may be subject to a preexisting condition exclusion for 12 months (18 months for late enrollees) after your enrollment date in your coverage. **The Fund's plan does not contain any exclusions for preexisting conditions.**

### Prudent Actions by Plan Fiduciaries

In addition to creating rights for plan participants ERISA imposes duties upon the people who are responsible for the operation of the employee benefit plan. The people who operate your plan, called "fiduciaries" of the plan, have a duty to do so prudently and in the interest of you and other plan participants and beneficiaries. No one, including your employer, your union, or any other person, may fire you or otherwise discriminate against you in any way to prevent you from obtaining a welfare benefit or exercising your rights under ERISA.



## EMPLOYEE RETIREMENT INCOME SECURITY ACT ("ERISA")

### IMPORTANT INFORMATION REQUIRED BY ERISA

1. The Plan Year starts on January 1 and ends on December 31, and consists of an entire calendar year for the purposes of accounting and preparing the reporting and disclosure information which must be submitted to the United States Department of Labor and other regulatory bodies.
2. The Plan is maintained by more than ten Collective Bargaining Agreements which are between the Teamsters Locals 107, 115, 169, 312, 326, 331, 384, 470, 500, 623, 628, 676 and 929 and various employer associations that have entered into labor contracts with these Local Unions.
3. The Plan is funded through employer contributions, the amount of which is specified in the Collective Bargaining Agreement between your employer and your Local Union.
4. Your Collective Bargaining Agreement may be reviewed at the Fund Office.
5. Upon written request, the Administrator will furnish you with information as to whether a particular employer participates in the Plan and, if so, his address.
6. This Plan provides comprehensive Hospitalization, Surgical, Medical, Dental, Vision, Death and Dismemberment, Short-term Weekly Disability and Prescription Drug Benefits. Please refer to the Table of Contents and the Summary of Benefits Schedule for more information concerning the benefits provided under this Plan.

### IMPORTANT INFORMATION REQUIRED BY ERISA

As a participant in the Fund you are entitled to certain rights and protections under the Employee Retirement Income Security Act of 1974 (ERISA). ERISA provides that all plan participants shall be entitled to:

#### Receive Information About Your Plan and Benefits

Examine, without charge, at the plan administrator's office and at other specified locations, such as work sites and union halls, all documents governing the plan, including insurance contracts and collective bargaining agreements, and a copy of the latest annual report (Form 5500 Series)

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d. You become eligible for Medicare; or

e. They are no longer considered dependents under the provisions of the Fund's Plan of Benefits.

It is the responsibility of the person who will lose coverage to inform the Administrator of a divorce, separation or a loss of dependent child status. The Administrator must be notified, in writing, within sixty (60) days after one of these events occur. If the Administrator is not notified, then that person will not be able to elect to continue his or her coverage.

Once the Administrator is notified of an event that affects the coverage of a Qualified Beneficiary, the Qualified Beneficiary will be notified that he has the right to choose continuation coverage. He or she then has at least sixty (60) days from the date he would lose coverage to let the Administrator know that he wants to continue coverage. If the Qualified Beneficiary did not choose it, the right to continue the group health coverage would then end. If he or she does choose it, he will be offered the right to continue the same coverage he was receiving the day before he lost coverage, except for the Death Benefit, Accidental Death and Dismemberment Benefit and Weekly Disability Income Benefits. Each Qualified Beneficiary can make a separate choice on whether to continue coverage. However, one person can make an effective choice to continue coverage for everybody. You can choose to continue only your core benefits - hospital, medical, surgical and prescription drug benefits - or these benefits plus your non-core benefits - vision and dental benefits.

**Please Note:** You are not eligible for COBRA continuation coverage if you have elected Extended Major Medical coverage as described on page 8 of this booklet. By the same token, if you elect COBRA coverage, you will not be eligible for Extended Major Medical coverage.

#### Certificate of Former Coverage

If you or your dependents lose coverage under the Plan, you will receive a certificate of former coverage. You may need the certificate if your new plan excludes coverage for pre-existing conditions. If you are entitled to COBRA coverage, the certificate will be mailed when a notice for a qualifying event under COBRA is required, and after COBRA coverage stops. You may request another copy of the certificate within 24 months of losing coverage.

If coverage ended because you left employment, or no longer meet the eligibility requirements, coverage may continue for up to 18 months. If coverage ended for any other reason, then coverage may be continued for up to thirty-six (36) months. These time periods may be shortened if:

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tially all of the normal activities of a person of like age and sex in good health solely because of injury or disease.

**Usual Charge:** The most consistent charge by an individual physician or provider of service to patients for a given service.



- a. The Fund no longer provides group health coverage for any employee;
- b. You do not pay the required premium in a timely fashion;
- c. You are later employed and are covered by another group health plan that does not contain any exclusion or limitation with respect to a pre-existing medical condition that is applied by the plan;
- d. You become eligible for Medicare; or
- e. You are divorced, subsequently remarry and are covered under your new spouse's group health plan.

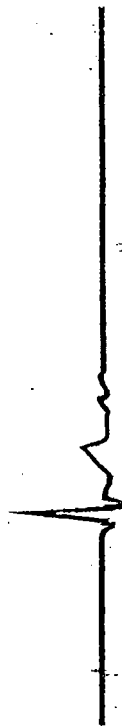
#### **Special Rule for Multiple Qualifying Events**

If you elect continuation coverage following a termination of employment or reduction in hours and, during the 18 month period of continuation coverage, a second event (other than a bankruptcy proceeding) occurs that would have caused you to lose coverage under the Plan (if you had not lost coverage already), you may be given the opportunity to extend the period of continuation coverage to a total of 36 months. If you elected continuation coverage as the spouse or dependent of a covered employee who experienced a termination of employment or reduction in hours and, during the continuation period the employee or former employee becomes entitled to Medicare, you may be given the opportunity to extend coverage for 36 months from your initial qualifying event.

#### **Special Rule for Totally Disabled Qualified Beneficiaries**

The 18-month period of continuation coverage may be extended for an additional 11 months (up to a total of 29 months), for any individual who is determined to have been disabled (for Social Security purposes) at the time your work hours were reduced, or your employment ended, or any time during the 18 month period during which you are enrolled in the COBRA program. To qualify for this additional coverage, the individual must provide the Plan with notice, within the 18-month coverage period, of Social Security's disability determination, and must remain disabled throughout the additional coverage period. The premium cost for COBRA continuation during the additional coverage period will be approximately 50 percent higher.

If you have any questions about this continuation coverage, please contact the Fund Office.



## HOW TO FILE A CLAIM

Much of the delay in processing claims can be directly related to incomplete or incorrectly completed claim forms being submitted to the Fund. If you follow the instructions outlined below, you will be helping the Fund provide you with the fastest claim service possible.

The benefits described in this Booklet have a heading for each type of benefit and state who may be covered for that benefit (for example, "Member only," "Member and Spouse only," etc.). For any limitations in your particular plan, please refer to the Summary of Benefits Schedule.

When a Claim Form is Not Needed:

- a. For those members enrolled in the Fund's Blue Cross program, present your Independence Blue Cross/Teamsters identification card to the hospital admission clerk. The card may only be used instead of a claim form if: (1) you are presently eligible for benefit coverage; and (2) you are receiving services in the hospital either as an inpatient or outpatient. NOTE: If you are enrolled in the Fund's *Traditional* program, only hospital charges are covered under the Blue Cross Program. You must file a claim directly with the Fund office for charges billed by a physician. If you are enrolled in the *Personal Choice™* or *Keystone HMO™* Programs, you card is used for both hospital and non-hospital charges - no claim form is necessary unless you are seeking services from an "Out-of-Network" provider.
- b. If you are receiving outpatient x-ray services through the Fund's Preferred Provider Organization administered by Health Care Solutions, call HCS' central phone number to receive a referral number to give to the diagnostic center when you go for your diagnostic test. All further billing will then be handled automatically.

IN ALL OTHER CASES, USE A CLAIM FORM AND FOLLOW THE INSTRUCTIONS AND GUIDELINES SET FORTH BELOW.

### 1. GENERAL INSTRUCTIONS:

- a. Claim forms may be obtained from the Fund Office, from your Local Union or from your Employer.
- b. Use a separate claim form for each Family Member.
- c. Use a separate claim form for each Provider of Service.

behalf of a participant or beneficiary, from any person or persons, party or parties, insurance company, firm, corporation, or government agency, whether by suit, judgment, settlement, compromise, or otherwise, the Fund, with or without the signing of a subrogation agreement, shall be entitled to immediate reimbursement to the extent of benefits paid to or on behalf of the Member or Dependent. The Fund shall be first reimbursed fully by or on behalf of such Member or Dependent to the extent of benefits paid from the monies paid by any person or persons, party or parties, insurance company, firm, corporation, or government agency and the balance of monies, if any, then remaining from such subsequent recovery shall be retained by or on behalf of the Member or Dependent.

All Members and Dependents are obligated to cooperate with the Fund in its efforts to enforce its subrogation rights and to refrain from any actions which interfere with those efforts. This duty of cooperation includes (but is not limited to) the obligation to sign a subrogation agreement in a form prescribed by the Fund. The Fund shall have the right to take all appropriate actions necessary to enforce its subrogation rights in the event that a Member or Dependent refuses to sign a subrogation agreement, refuses to reimburse the Fund in accordance with the Fund's subrogation rights, or takes any other action inconsistent with the Fund's subrogation rights. In such situations, the Fund's options shall include, without limitation, the right in appropriate cases to deny benefits to an individual who refuses to sign a subrogation agreement; to institute legal actions to recover sums wrongfully withheld or to obtain other relief; and/or to offset wrongfully withheld sums against future benefit payments otherwise owed the individual who retains such sums. The Fund may pay counsel fees in an amount not to exceed 20% in order to protect the Fund's subrogation interests.

**Summary of Benefits Schedule:** This is the Insert which accompanies this Booklet, and contains the actual allowances for your various benefits. In addition, you will also find a partial listing of covered dental allowances in this Insert. You may write the Fund Office to learn the allowance of any covered procedure not listed. The maximum allowance may not exceed the fee actually charged for the procedure.

### Totally Disabled:

#### For Member:

You are prevented from engaging in your customary occupation solely because of injury or disease and are performing no work of any kind for pay or profit.

#### For Dependent:

Your dependent is prevented from engaging in substantial



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d. Check each charge and report any errors to the Fund immediately.

e. **MOST IMPORTANT:** Care in filling out your claim form is important. Make sure each appropriate section is completed in full. A great deal of the delay in processing a claim is the result of our having to return claims to busy physicians or members for missing information. Be particularly accurate when writing names, dates of birth, social security numbers, accident information, etc.

f. **PAYMENT TO DOCTOR OR HOSPITAL-**  
If you wish payment to be made directly to the Provider of Service, sign the appropriate "Assignment of Benefits Statement" contained on the claim form.

g. **PAYMENT DIRECTLY TO YOU-**  
If payment is to be made to you, please attach an original, itemized bill (not a copy) on the physician's or hospital's stationary to the claim form, along with a paid receipt to verify charges and payment.

h. **BE SPECIFIC-**  
Have your physician provide a detailed bill listing the following: diagnosis, dates of treatment, treatment performed, and charges for each treatment.

## 2. FOR MEDICAL EXPENSES:

For your convenience, the Fund has developed a single claim form which may be used for most of your medical expenses. These forms may be obtained either from the Fund Office or from your Local Union. All you need to do is check the appropriate block at the top of the claim form and follow the instructions given above to obtain your benefits.

## 3. FOR WEEKLY DISABILITY BENEFITS:

a. You may use the same claim form you would use for obtaining your medical expense benefits, only please be sure a separate claim form is used for any charges being made by the attending physician.

b. Be very certain your doctor has completed his section in full, excluding his charges for services (the doctor's charges must be submitted on a separate claim form).

**Reasonable Charge:** A fee is reasonable when it meets the Usual and Customary criteria or it may be reasonable if in the opinion of an appropriate Medical Review Committee it merits special consideration based on complexity of treatment of the particular case.

**Special Care Facility:** An institute other than a Hospital (as defined in this Booklet) which:

1. specializes in physical rehabilitation of injured or sick patients, or
2. specializes in the diagnosis and treatment of mental illness or functional nervous disorders, or
3. specializes in the diagnosis and treatment of alcoholism, drug addiction or mental and nervous disorders.

In addition, to qualify as a Special Care Facility, an institution must be:

- a. legally licensed to give medical treatment, and
- b. operated under the supervision of a physician, and
- c. offer nursing service by registered graduated nurses or licensed practical nurses.

However, the term "Special Care Facility" does not include an institution or part of one that is used mainly as a facility for rest, convalescence, or for the aged.

**Spouse:** Means either your lawful wife or your lawful husband. The status of spouse shall be determined exclusively with reference to the laws of the Commonwealth of Pennsylvania regardless of the residence or domicile of the parties involved. Additionally, whether you are "separated" from your spouse will be determined with reference to the laws of the Commonwealth of Pennsylvania regardless of the residence or domicile of the parties involved.

**Subrogation of Benefits:** The following rule applies to any situation in which the Fund makes any full or partial payment to or on behalf of a Member or Dependent (other than for death benefits) who subsequently recovers from any other source additional payments or benefits in any way related to the accident, illness, or treatment for which the Fund made full or partial payment. Upon any such subsequent recovery by or on

- c. Have your employer complete the Company Statement section on the back of the claim form.

**4. FOR DEATH BENEFITS:**

- a. Death of Member-  
Use the Death Benefit claim form. Complete the patient information section of the form and attach a certified copy of the death certificate.
- b. Death of Spouse-  
Same information as described above, plus a copy of your marriage certificate.
- c. Death of a Child-  
Same information as for death of a member, plus a copy of the child's birth certificate.

**5. FOR MEMBER TOTAL DISABILITY EXTENDED DEATH BENEFITS:**

This is a special form obtained only from the Fund Office. This form must be completed yearly in order to qualify for coverage.

**6. FOR VISION BENEFITS:**

The Vision Form may be obtained from the Fund Office or your Local Union.

**7. FOR PHARMACY BENEFITS:**

Use your Prescription Drug Card when obtaining your prescription. If the pharmacy does not accept your card, you may still have your prescription filled (or refilled) and file a completed "Direct Pay Card" with the Fund. The "Direct Pay Cards" are obtained from the Fund Office for reimbursement by the Pharmacy Card Company. Keep in mind that when using the "Direct Pay Cards" your deductible may be larger because your druggist is charging you whatever the market will bear, but the Pharmacy Card Company will only pay you the Usual, Customary and Reasonable allowance for the prescription.

**8. FOR DENTAL BENEFITS:**

Because most of the Fund's eligible participants have been receiving dental treatment on a regular basis, all you need generally do to obtain a Dental Claim Form is call the Fund Office. If, however, any of the fol-

The masculine pronoun whenever used shall include the feminine pronoun and the singular shall include the plural where appropriate.

**Out-of-Pocket Expense:** Under the Fund's Major Medical Plan, you share in the cost of treatment up to a certain amount. The maximum Out-of-Pocket expense that you must pay is shown in the Summary of Benefits Schedule that accompanies this Booklet. Once your Out-of-Pocket share has been satisfied, the Fund would generally begin to pay 100% of your Covered Expenses, subject to any other Plan limits. Your Out-of-Pocket expense is not recoverable from the Fund.

**Participating Local Union:** A union with whom any of the contributing employers have entered into a signed Collective Bargaining Agreement, as a requirement of which, the employer is obligated to make contributions to the Fund on behalf of the employees covered by that Collective Bargaining Agreement.

**Physical Examination:** The Fund reserves the right to examine at its own expense and as often as necessary, any person whose injury or sickness is the basis of a claim and, in the case of any death claim, to have an autopsy made.

**Physician:** Means a doctor of medicine (M.D.), a doctor of osteopathy (D.O.), a doctor of chiropractic medicine (D.C.), a doctor of dental surgery (D.D.S.), a doctor of dental medicine (D.M.D.), a doctor of podiatric medicine (D.P.M.), and optometrist (O.D.). A clinical psychologist (Ph.D., M.S., or M.A.), when providing treatment for mental illness or functional nervous disorders, shall also be considered a physician.

**Plan:** Means this Booklet, the applicable Summary of Benefits Schedule and any modifications thereto published by the Teamsters Health and Welfare Fund of Philadelphia and Vicinity duly adopted by the Fund's Board of Trustees in accordance with their authority set forth in the Agreement and Declaration of Trust establishing the Fund. Additionally, the Trustees of the Fund, by unanimous action, may terminate, suspend, withdraw, amend or modify the benefits available under the Fund, in whole or in part, at any time and without any prior notice. Any such termination, suspension, withdrawal, amendment or modification of benefits shall not require the consent of any employer, union, Member or Dependent, nor shall such action require individual notice to any such person or organization.

**Prescription:** A written order of a physician or where permitted by law, an oral order of a physician, for legend drugs to the extent that such order is within the scope of such physician's license.

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**Medically Appropriate or Medically Necessary:** Means services or supplies that are:

1. appropriate for the symptoms and diagnosis or treatment of the Family Member's condition, illness, disease or injury; and
2. required for the diagnosis, or the direct care and treatment of the Family Member's condition, illness, disease or injury; and
3. in accordance with standards of good medical practice as generally recognized and accepted by the medical community; and
4. not primarily for the convenience of either the Family Member's family or a provider of medical services; and
5. the most efficient and economical supply or level of service that can safely be provided to the Family Member. When applied to hospitalization, this further means that the Family Member requires acute care as a bed patient due to the nature of the services rendered or the Family Member's conditions, and the Family Member cannot receive safe and adequate care in some other setting without adversely affecting the Family Member's condition or quality of medical care.

**Medicare:** To the extent permitted by law, Medicare benefits will be taken into account for any Member or Dependent while they are eligible to apply for Medicare, whether or not they actually apply. The Fund will determine a Family Member's benefit allowance, if any, based upon the applicable Medicare statutes and regulations.

**Member (or Eligible Member):** An individual who has satisfied the eligibility requirements based on contributions made on his behalf by his Employer to the Fund and has qualified for the benefit program. Members include the following types of employees: (1) an employee covered by a collective bargaining agreement which requires his employer to contribute to the Fund on his behalf, (2) an employee of a Labor Union or trade association which contributes to the Fund on his behalf and (3) an employee of the Fund or the Teamsters Pension Trust Fund of Philadelphia and Vicinity who has contributions paid to the Fund on his behalf.

lowing conditions exist, you may be required to be examined by a dentist selected by the Fund prior to beginning treatment:

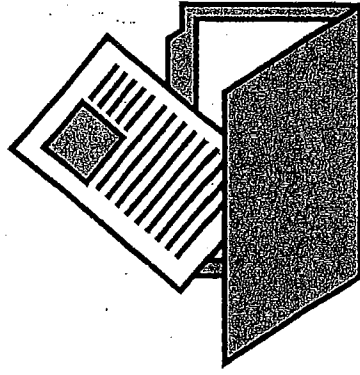
- a. Orthodontia (Braces) are anticipated (children 10 to 18 years of age only).
- b. You are randomly selected as a part of the Fund's Dental Audit Procedure.
- c. Periodontal Care is anticipated.
- d. Temporomandibular Joint Disorders.

**9. HOW SOON SHOULD YOU FILE YOUR CLAIM? As soon as you can!**

Written proof of loss must be furnished to the Fund within ninety (90) days after the date of such loss. Failure to furnish said proof within such time shall not invalidate or reduce any claim if it was not reasonably possible to give proof within such time, providing the Fund's liability position has not been prejudiced by the late filing.

All benefits provided by the Fund will be paid promptly upon receipt of proof of loss. Any benefit payable for loss of the Member's life will be payable to the Member's beneficiary; other benefits will be payable to the member, or the member may assign these other benefits to the provider of service.

In the event of an overpayment, either to you or to a "provider of service" on your behalf or on a Family Member's behalf, the Fund reserves the right to reduce subsequent Family Member benefit payments by the amount of such overpayment.



Trustees shall have the right to finally determine whether or not a fraud has been attempted or committed upon the Fund or if a misrepresentation of fact has been made, and its decision shall be final, conclusive and binding upon all persons.

**Fund:** The Teamsters Health and Welfare Fund of Philadelphia and Vicinity.

**Group Therapy:** Is not covered unless the only other participants in the "group" are other Family Members. In addition the therapy must be performed by a physician as defined in this Booklet and be related to treatment of a mental illness, a functional nervous disorder, drug abuse or alcoholism. Regardless of the number of Family Members participating in the therapy session, only a single individual allowance will be made per session.

**Hospitals:** An acute care institution which meets the following requirements:

1. Is licensed as a Hospital by the State in which it is located, and the primary function of the institution is providing inpatient medical care and treatment through medical diagnostic and major surgical facilities on its premises under the supervision of a staff of physicians, and with 24 hour a day nursing service, and
2. Is not owned or operated by the United States Government or by a State (or political subdivision thereof) unless there is an unconditional requirement that persons receiving care must pay for such care.

However, "Hospital" does not include a Nursing Home or an institution, or part of one, used primarily as a facility for convalescence, rehabilitation, treatment of mental illness or functional nervous disorders, a place for the aged, a rest home, a place for alcoholics, or place for drug addicts.

**Inpatient:** An individual who, while confined in a Hospital or Special Care Facility, is assigned to a bed in any department of the institution other than its outpatient department and for whom a charge for room and board is made.

**Legend Drugs:** Drugs, biologicals, and compounded prescriptions which, by Federal Law can be dispensed only pursuant to a prescription, and are required to bear the legend, "Caution: Federal Law prohibits dispensing without a prescription."

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No action at law or in equity shall be brought to recover the allowable benefits prior to the expiration of sixty (60) days after proof of loss has been furnished nor shall such action be brought at all unless brought prior to December 31st of the third year immediately following the year in which the loss was incurred.

#### DEATH BENEFIT

FOR MEMBERS AND DEPENDENTS

#### BENEFIT (Occupational and Non-Occupational)

In the event of your death from any cause, payment of your death benefit will be made to your beneficiary of record. In the event of the death of any other covered Family Member, payment will be made directly to the member. The amount of payment is that shown in the Summary of Benefits Schedule.

A payment of all or a portion of the death benefit may be made directly to a funeral home, provided the Fund receives from the beneficiary of record an appropriate, written and signed assignment of benefits.

#### CONTINUANCE OF MEMBER DEATH BENEFIT IN THE EVENT OF TOTAL DISABILITY

If, while you are eligible, you become totally disabled, your Death Benefit coverage as determined from the Summary of Benefits Schedule will continue after your eligibility stops provided:

1. You must provide the Fund with written proof, satisfactory to the Trustees or the appropriate Fund representatives, that you are Totally Disabled. THIS WRITTEN PROOF MUST BE PROVIDED TO THE FUND WITHIN SIX MONTHS OF THE DATE ON WHICH YOU FIRST RECEIVED ORAL OR WRITTEN NOTICE FROM THE SOCIAL SECURITY ADMINISTRATION, A PHYSICIAN, A HEALTH PROVIDER, OR ANY OTHER SOURCE THAT YOU ARE TOTALLY DISABLED. Contact the Fund Office for this special form.
2. During the last three months of each subsequent year that you remain Totally Disabled, you must provide the Fund with written proof of your continuing disability. This written proof shall be in a form satisfactory to the Trustees or the appropriate Fund representative.
3. If you die before the expiration of the six month period set forth in paragraph (1) above, then within one year of your death your beneficiary of record must provide the Fund with written proof that you

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plans shall not exceed the total of the Usual, Customary and Reasonable charges for the service provided.

- g. If a dependent spouse is eligible to enjoy group coverage through his/her employer at no cost to him/her, the spouse must enroll for such coverage (single coverage only). Furthermore, if such coverage exists for the spouse at no cost to him/her, the spouse may not waive coverage in lieu of a salary increase or other financial remuneration.

**Counseling:** It is not a covered benefit unless it is performed by a physician as defined in this Booklet. In addition, the counseling must be related to the patient being treated for a mental illness and/or functional nervous disorder, drug abuse and alcoholism. The counseling must also be performed in a non-group setting, unless the other participants are Family Members, in which case the Fund would still only provide a single individual benefit allowance per session.

**Covered Expenses:** Only actual charges for an item or service which is specifically listed as a covered benefit under a provision of the Plan which is covered by your specific Summary of Benefits Schedule which accompanies this Booklet.

**Customary Charge:** A fee is Customary when it is within the range of usual charges for a given service billed by most physicians or providers of service with similar training and experience within a given area.

**Deductible:** A specified amount of Covered Expenses for the Covered Services that is incurred by the Covered Person before the Fund will assume any liability.

**Dependent:** (See Eligibility Provisions in the front of this Booklet.)

**Family Member:** (See Eligibility Provisions in the front of this Booklet.)

**Fraud:** No benefits under this Plan will be paid if the person on whose account, or by whom the benefit is claimed, or the provider of service attempts to perpetrate a fraud upon or misrepresents a fact to the Fund with respect to any such claim. In the case of such conduct, the Board of Trustees, may, in its sole and exclusive discretion, pay no further benefits to the member, dependent or beneficiary involved as to the particular claim or as to any other claims arising during a period of not more than one year after the discovery of such fraud, attempted fraud or misrepresentation. The Fund shall have the right to fully recover any amounts, with interest, improperly paid by the Fund by reason of fraud, attempted fraud or misrepresentation of fact by a member, dependent, beneficiary or provider of service and to pursue all other legal remedies. The Board of

remained Totally Disabled from the onset of the total disability to the date of your death.

4. If you apply for disability benefits from the Social Security Administration at any time after you cease working, then you must send a copy of your application and all supporting documentation to the Fund within ninety (90) days after you file the application with the Social Security Administration.

## BENEFICIARIES

1. You have the sole right to designate the beneficiary to whom your Death Benefit shall be payable. This designation is one of the records which the Fund Office maintains along with your census information. Also, you can change your designation at any time, but you must do this in writing and it will take effect on the day your signed request is received in the Fund Office.
2. If you have more than one beneficiary when you die, and you haven't specified their respective interests, they all share equally.
3. If any beneficiary dies before you do, his or her rights and interest shall automatically terminate.
4. If your designated beneficiary does not file a claim for your Death Benefit within one year from your date of death and the whereabouts of this designated beneficiary are unknown, the Fund shall insert an advertisement in a newspaper of general circulation in the last known place of residence of this designated beneficiary as shown by the Fund's records, to the effect that if the designated beneficiary does not file a claim within ten (10) days of the advertisement, the Trustees will pay your Death Benefit, without interest, to your estate or next of kin as set forth below.
5. If you have not designated a beneficiary or the beneficiary you named is no longer living or fails to file a Death Benefit claim after the advertisement described above, then the Fund may, at its option, pay an amount not to exceed \$1,000.00 to any person or persons who may have incurred expenses in connection with your last illness or burial. The balance of your Death Benefit, if any, shall be paid to:
  - a. Your surviving spouse, or, if none,
  - b. Equally to your surviving children, or, if none,
  - c. Your parent(s), or, if none,
  - d. The personal representative of your estate without restriction to the foregoing order.

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**MEMBER ACCIDENTAL, DEATH  
AND DISMEMBERMENT BENEFIT**

FOR MEMBERS ONLY

**BENEFIT**

(Occupational and Non-Occupational)

1. If, as a result of external, violent and accidental bodily injury, you suffer the loss of life, limb or sight, and if such loss occurs within twenty-six (26) weeks following the date of the accident, payment will be made of the benefit specified in the Summary of Benefits Schedule upon receipt of due proof of such loss.
2. Payment will be made for each loss without regard to previous losses, provide that the total amount payable due to two or more losses sustained by you in all accidents does not exceed the principal sum as determined in the Summary of Benefits Schedule.

**LOSSES COVERED**

LOSSES COVERED	AMOUNT OF BENEFIT
Loss of Life	
Both Hands or Both Feet	
Sight of Both Eyes	
One Hand and One Foot	
One Hand and Sight of One Eye	
One Foot and Sight of One Eye	
One Hand or One Foot	
Sight of One Eye	

Loss of Sight means: Total and irrecoverable loss of sight. Loss of Hand or Foot means: Loss by severance at or above wrist or ankle.

**LIMITATIONS**

Claim Date is the date of death or, in the event of loss of sight or dismemberment, the date of the accident.

Accidental Death and Dismemberment does not cover any loss resulting from or caused directly, in whole or in part, by:

- a. Disease or bodily or mental infirmity or medical or surgical treatment thereof.
- b. Ptomaines or bacterial infections, except pyogenic infections occurring with and through an accidental wound,
- c. Suicide or intentionally self-inflicted injury, while sane or insane,

(ii) In the absence of such a court order establishing such financial responsibility, the following shall be the order of payment of benefits for such dependent child:

Parents Separated or Divorced - Not Remarried

1. Plan covering Parent with Custody
2. Plan covering Parent without Custody

Parents Separated or Divorced and Remarried

1. Plan covering Parent with Custody
2. Plan covering Step-Parent with Custody
3. Plan covering Parent without Custody

4. The Fund's Plan will not provide any benefit if the person for whom the claim is made is a pensioner, or the dependent of a pensioner who is gainfully employed and his employer provides him with health insurance or the person for whom the claim is made is not a member, or an eligible dependent of a member.

5. If the rules set forth above do not establish the order of benefit payment, the plan which covered the person for whom the claim is made for the longer period of time shall be considered the primary source of benefits.

c. Medicare Coverage-For Covered Expenses incurred by Members and/or Dependents age 65 through 69 years, except for dependents age 65 through 69 of Members over age 69, the coverage provided by the Fund is primary. In all other situations, Medicare coverage is primary and the Fund is secondary.

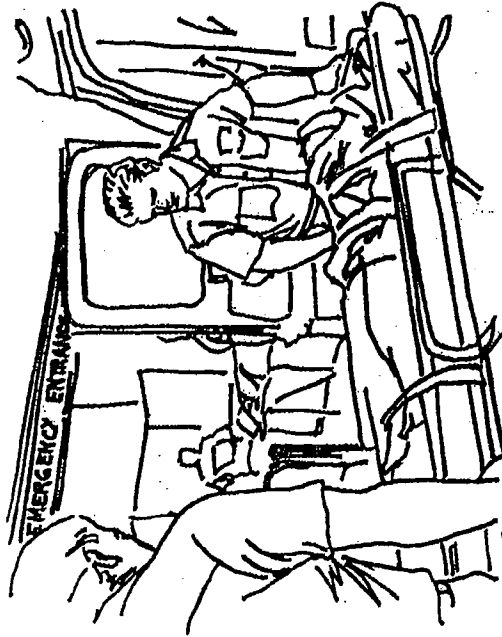
d. Under no circumstances will the Fund pay any benefits as the primary plan when a member or the dependent of a member has elected to make the Fund the primary plan by waiving coverage under any other plan. This provision shall be effective regardless of whether the dependent waived enrollment in such other plan (when required to enroll in circumstances described in paragraph g. below) or, if enrolled, sought or secured services outside of the required network of providers of such other plan.

e. If a group plan provides benefits in the form of services rather than cash payments, the reasonable cash value of each service rendered shall be deemed a benefit payment.

f. Benefits otherwise payable under the Fund's Plan shall be reduced in accordance with the above priorities of payment to the extent necessary so that the sum of such reduced benefits payable under all group

THWFO021

- d. Participation in or in consequence of having participated in an illegal act which is in violation of any federal or state criminal statute,
- e. Flying, unless you were a passenger on a commercial airline,
- f. War or any act of war, whether declared or undeclared, or insurrection,
- g. Drug overdose, whether intentional or unintentional.



1. *Member of the Fund:* The Fund will provide primary coverage for Members of the Fund, and (in each case) the other plan will provide secondary coverage for such Members. This provision will not apply to pensioners under age 65 who are gainfully employed and covered by a plan provided by their employer; such individuals are covered by paragraph 4 below.

2. *Dependent Spouses:* In each case, the other plan will provide primary coverage for the dependent spouse, and the Fund will provide secondary coverage for the dependent spouse.

3. *Dependent Children:*

(a) If a dependent child is gainfully employed and is covered by another plan as a result of that employment, then no coverage is available under the Fund's plan for such dependent child.

(b) If paragraph 3(a) above is not applicable and the member and the child's other parent are married to each other and not separated, then the "birthday rule" shall apply. Under the birthday rule, the Fund will provide primary coverage if the member's birthday occurs before the spouse's birthday during the calendar year. For example, if the member was born in June and the spouse in September, then the Fund will provide primary coverage and the spouse's plan will provide secondary coverage. On the other hand, if the spouse's birthday occurred earlier in the calendar year than the member's birthday, then the spouse's plan will provide primary coverage and the Fund will provide secondary coverage. If the member and the spouse have the same birthday in the calendar year, then provision (5) below will apply.

(c) If paragraph 3(a) above is not applicable and the member and the child's other parent are either separated or divorced from each other, then the following rules shall apply.

(i) If there is a court order which establishes or apportions the parents' respective obligations to provide for the medical, dental or other health care expenses of any such child, then benefits will be apportioned in accordance with the provisions of the court order, provided that such court order cannot grant benefits which are not otherwise provided by the Fund.

**WEEKLY DISABILITY BENEFIT**

FOR MEMBERS ONLY

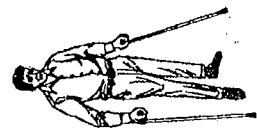
**BENEFIT  
(Non-Occupational)**

1. If you, prior to retirement, become disabled from a non-occupational accidental injury or disease, and will be prevented by such disability from performing any and every duty pertaining to your occupation, upon receipt of a Weekly Disability claim form, containing proof of disability satisfactory to the Trustees, payment will be made to you as determined from the Summary of Benefits Schedule and continue for the duration of the disability, for the maximum shown in the Summary of Benefits Schedule during any one continuous period of disability whether from one or more causes.
2. Successive periods of disability will be considered as having occurred during one period of disability unless the subsequent period is due to causes completely and entirely unrelated to the prior accident or disease or unless the prior and subsequent periods are separated by a resumption of active employment for a period of thirty (30) or more full calendar days.

3. Benefits are payable only while you are under the care of, and treated personally by, a legally qualified physician or surgeon.

**LIMITATIONS**

1. Disability must commence while you are covered for this benefit.
2. This benefit is paid in lieu of wages.
3. Claim date is determined from the date you are first seen and treated by a physician.
4. Your Weekly Disability Benefit will be coordinated with any short-term disability or wage loss benefit payable to you under any applicable automobile no-fault policy, program, law or regulation.



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**Claim Review Procedure:** See "Your Rights and Protections under ERISA" in this Booklet.

**Collective Bargaining Agreement:** As a requirement of which the employer is obligated to make contributions to the Fund on behalf of the employees covered by that Collective Bargaining Agreement.

**Contributing Employer:** An employer whose signed Collective Bargaining Agreement requires the employer to make contributions to the Fund on behalf of the employees covered by the terms of that Collective Bargaining Agreement.

**Coordination of Benefits (C.O.B.):** The Teamsters Health and Welfare Fund's Plan provides for Coordination of Benefits. This means that should a Family Member be entitled to any medical, dental, vision, disability or pharmacy benefits from another source, benefits under this Plan may be reduced to an amount, which together with all such other coverage under any other plan or policy, will not exceed 100% of any Usual, Customary and Reasonable item of expense covered under this Plan or any other such plan. The Fund has special rules for coordinating benefits with respect to automobile insurance. These rules are explained under the heading "Automobile Insurance" which is defined earlier in this section. The Fund also has a special rule for situations in which you are covered by a group or individual medical insurance policy, other than an automobile insurance policy, which requires you or any member of your family to pay the entire premium. In that event, should you or any of your Family Members be hospitalized, the Fund will pay to you a set daily allowance which is contained in your Summary of Benefits Schedule.

In all other cases in which a Family Member, on whose behalf a claim is submitted, is covered under one or more group plans for health benefits in addition to the Fund's Plan, benefits will be coordinated so that the member may receive up to 100% of the Reasonable and Customary Charges in accordance with the following priorities of payment:

- a. If the other plan providing benefits for a person covered under the Fund's Plan does not have a coordination of benefits or duplication of benefits provision, benefits payable for covered expenses under the other plan will be paid in full before any benefits are paid by the Fund's Plan.
- b. If the other plan providing benefits for a person covered under the Fund's Plan does have a coordination or non-duplication provision, the following rules will apply for determining whether the Fund or the other plan will provide primary coverage. For the purposes of these rules, the plan which provides "primary coverage" shall be obligated to provide benefits to the fullest extent of its coverage before any other plan is obligated to cover the benefits in question. The plan which provides "secondary coverage" shall not be obligated to provide benefits until the "primary coverage" is exhausted.

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## GENERAL PROVISIONS AND DEFINITIONS

**Accidental Bodily Injury:** For an injury to be considered an accident, the injury must have resulted from some external, violent and unforeseen happening.

**Actual Charges:** Shall mean covered charges up to the Usual, Customary and Reasonable charges as defined in this Section, and never to exceed the payment the provider of service accepted as payment in full from any other source.

**Assignment:** The Member or his/her Spouse have the right to authorize the Fund to pay a Family Member's benefits directly to the physician or hospital who provided the Family Member with covered care and treatment. Except for this, however, you may not assign, alienate, anticipate or commute any benefits which a Family Member is entitled to receive from the Plan and, further, except as may be prescribed by law, none of your benefits shall be subject to any attachments or garnishments of or for your debts and/or contracts, etc., except for recovery of overpayments made on a Family Member's behalf by the Fund, as described under the HOW SOON SHOULD YOU FILE YOUR CLAIM paragraph in the How To File a Claim section of this Booklet.

**Automobile Insurance:** Where an injury is caused by an accident that is covered by a State-required Automobile Insurance Law, the coverage under this Plan is secondary and the automobile insurance or Assigned Claims Plan is responsible to pay the covered charges for that injury first. The Plan will then cover the balance of the covered charges that were not covered by the automobile insurance, up to the maximum benefit level set forth in the Summary of Benefits Schedule insert.

Special additional exclusions apply in the case of No-Fault insurance policies that are governed by the New Jersey No-Fault Law, as amended by the New Jersey Insurance Freedom of Choice and Cost Containment Act. Participants, dependents and beneficiaries who are injured in the course of an automobile accident and who are also covered by an automobile insurance policy governed by the New Jersey No-Fault Law, as amended by the New Jersey Automobile Insurance Freedom of Choice and Cost Containment Act, may only be reimbursed under the Plan by the Fund up to a maximum of \$1,000 per accident for Covered Expenses and, in the case of an eligible member, only up to a Weekly Disability maximum of \$50 per week up to the Plan maximum of twenty-six (26) weeks.

**Claim Forms:** The Fund, upon receipt of a written notice of claim, will furnish to the claimant such forms as are usually furnished by it for filing proof of loss. If such are not furnished within 30 days after the giving of notice, the claimant shall be deemed to have complied with the requirements of the Fund for submitting proof.

## FOR MEMBER AND DEPENDENTS

## HOSPITAL EXPENSE

### BENEFITS (Non-Occupational)

#### Room And Board

The maximum amount payable for each day of confinement is the room and board daily maximum shown in the Summary of Benefits Schedule. The benefit will be payable until the expiration of the maximum period of payment shown in the Summary of Benefits Schedule. The full cost of a private room will be allowed when a patient's condition requires isolation for his own health or that of other patients and if ordered and certified by the attending physician prior to the time he is placed in the private room. Proof of the medical condition necessitating a private room must be supplied to the Fund.

#### Miscellaneous Covered Expenses

The maximum amount payable during one continuous period of hospitalization is the maximum for Miscellaneous Covered Expenses shown in the Summary of Benefits Schedule.

The charges for Miscellaneous Services and Supplies for which hospital expense benefits are payable are the following:

1. Charges by the hospital for medical care and treatment, provided such care and treatment is necessary for the treatment of the illness/injury for which you are confined, and which are normally billed by and payable to the hospital.
2. Charges by a professional ambulance service, for which a benefit is payable under the Hospital Expense or Out-Patient Emergency Accident provision of this Plan, but not to exceed the amount set forth in the Summary of Benefits Schedule.
3. This benefit also covers the charges for miscellaneous expenses and facility charges related to surgery you have on an outpatient basis at an accredited hospital.

#### CONTINUOUS PERIOD OF CONFINEMENT

Successive periods of confinement will be considered as one continuous period of confinement unless:

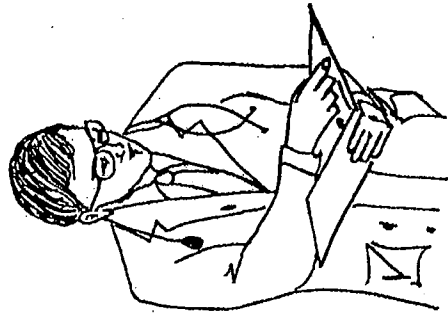
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1. The subsequent confinement is due to an accidental bodily injury or disease entirely unrelated to the cause of the prior confinement, or
2. In the case of a member, the subsequent confinement commences after the member has returned to active employment for a period of thirty (30) or more full calendar days, or the subsequent confinement commences more than ninety (90) calendar days after the end of the prior confinement, or
3. In the case of a dependent, the subsequent confinement commences more than ninety (90) calendar days after the end of the prior confinement and the dependent has resumed or begun normal life activities.

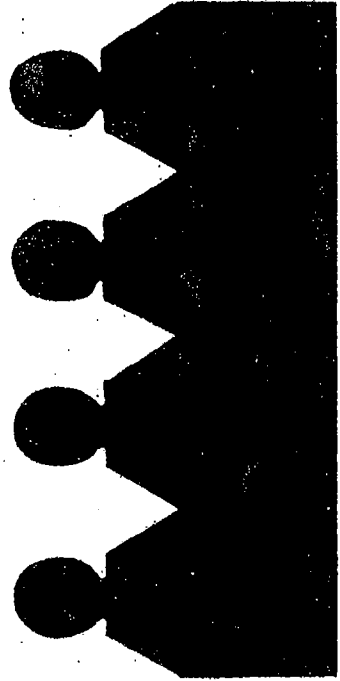
NOTE: As described in the "Managed Care" section which follows, the Fund may require that you obtain a Second Surgical Opinion for certain surgical procedures as a condition to providing full Hospital Benefits.

#### LIMITATION

In no event shall the number of reimbursable hospital days under the Basic Benefit program for any one illness or injury exceed the maximum allowable hospital days per disability or illness as set forth in the Summary of Benefits Schedule.



18. Charges for immunizations and vaccines (unless specifically covered under either the *Personal Choice™* or *Keystone HMO™* Programs)
19. Charges for eye exercises, psychological testing, and learning disabilities, school or DOT physicals.
20. Charges for Counseling (including marriage counseling) or group therapy. See definition of these terms in the following section for some exceptions.
21. Charges for treatment of temporomandibular joint dysfunction in excess of any coverage under the Fund's Dental Benefit Plan.
22. Charges for sex change operations.
23. Charges for penile prosthetic devices.
24. Charges for the surgical correction of myopia.
25. Charges for treatment of infertility, including, but not limited to, in-vitro fertilization, artificial insemination, gamete intra-fallopian transfer (GIFT), zygote intra-fallopian transfer (ZIFT) and/or reversal of a sterilization procedure.
26. Charges for any other medical, dental, vision, or pharmacy service except as provided in your appropriate Summary of Benefits Schedule.
27. Also, benefits will only be paid in accordance with provisions of the Fund's various Plans. For example, Vision Care is provided for under its Vision Care Plan and will not be provided under any other provision of the Plan unless specifically included in such other Plan provision.



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**IN-HOSPITAL PHYSICIAN VISITS**

This benefit is covered quite differently depending on the Plan under which you are covered. Some Plans do not have this coverage, other Plans pay a portion under this Benefit and also under the Major Medical Provision, if you have that coverage, and lastly some Plans provide coverage only under the Major Medical Provision. Consult your Summary of Benefits Schedule insert to determine your coverage.

**PRE-ADMISSION TESTING**

You May Be Able To Shorten Your Hospital Stay And Save Money Out Of Your Pocket

Whenever it appears that it will be necessary for the hospital to administer tests prior to surgery or to confirm a diagnosis, you may have these tests done on an outpatient basis, yet the Fund will pay them under the inpatient miscellaneous allowance in full. In order to be eligible for this benefit, the tests must be performed within one week of the scheduled surgery and must not be of a type which are routinely repeated prior to surgery. Following these rules could save you out-of-pocket expense in the form of deductibles and co-payments.

**LIMITATIONS**

As this coverage is intended for hospital expenses, benefits are payable only under the following conditions:

1. The Family Member must be confined in a hospital as prescribed by a licensed physician.
2. Confinement must commence while the Family Member is covered for this benefit. Date of claim is the date of admission to the hospital.
3. The hospital benefit covers miscellaneous charges only if they are incurred during a period for which benefits are payable for room and board charges, unless you have opted for the Pre-Admission Testing Benefit explained under that heading above.
4. Benefits for Alcoholism, Drug Abuse, Mental and Nervous Disorders have specific limitations. Please consult the Summary of Benefits Schedule for the actual allowances.

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6. Charges in excess of the payment the provider of service accepted as payment in full from any other source.

7. Charges for custodial care.

8. Charges for services rendered by a member of the patient's immediate family (including in-laws).

9. Charges that are made only because this coverage exists, or charges that no covered individual is legally obligated to pay.

10. Charges for treatments, services and/or supplies provided by the United States government, or any other government, unless you were legally required to pay for such treatments.

11. Charges resulting from war or service connected injuries or diseases.

12. Charges associated with any treatment for weight reduction.

13. Charges for hearing aids or the examination and fitting of hearing aids.

14. Charges to the extent that they are recovered from any person or organization other than an insurer of the patient.

15. Charges for cosmetic treatment and/or surgery for purposes other than breast reconstruction following a mastectomy, correction of damages caused by accidental injury, or for correction of a birth defect, providing that the patient was covered under this Plan on the date of the accident or date of birth and is still eligible as of the date of the cosmetic treatment or surgery. NOTE: SURGERY GENERALLY CONSIDERED COSMETIC IN NATURE (EVEN THOUGH FOR MEDICAL REASONS) REQUIRES PRIOR APPROVAL FROM THE FUND.

16. Charges for the diagnosis and treatment of dislocations, strains, sprains or misplacements of the skeletal structure (pertaining to the skeleton) or musculature (the system of muscles), except for the first fifteen (15) visits with a physician in any calendar year or when requiring the administration of a general anesthesia, an opening or cutting operation, or confinement in a hospital.

17. Charges for orthotic shoe inserts (unless specifically covered under your Summary of Benefits Schedule).

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## **SURGICAL AND ANESTHESIA EXPENSES**

### **SURGICAL EXPENSE BENEFIT (Non-Occupational)**

This benefit applies to the actual charges made by the operating physicians for surgical procedures, but will not exceed the amount shown in the Summary of Benefits Schedule or the Fund's Usual, Customary and Reasonable Allowance for that surgical procedure.

The Fund has a complete surgical schedule. In order to determine an allowance, if any, please have the surgeon submit to the Fund, in writing, a complete description of the procedure to be performed.

If more than one operative procedure is performed through the same incision during the course of a single operative procedure, the benefit will be the sum of the operative procedure providing the highest amount according to the Fund's Usual, Customary and Reasonable Allowance, plus 50% of the amount set forth in the Fund's Usual, Customary and Reasonable Allowance for the additional operative procedure. If more than one operative procedure is performed at the same time in separate operative fields and through separate incisions, each procedure is paid at the Fund's Usual, Customary and Reasonable Allowance.

Assistant surgeon's charges are only covered under Major Medical, if medically necessary, and a qualified intern, resident, or other in-house physician is not available.

### **SUCCESSIVE OPERATIVE PROCEDURE**

All surgical procedures will be considered as having been performed during one continuous period of disability unless evidence is furnished that:

1. The latest procedure is due to causes entirely unrelated to the causes of all previous surgical procedures, or
2. In the case of a member, the subsequent operative procedure was performed after the member had returned to active employment for thirty (30) or more full calendar days, or the subsequent operative procedure occurs more than ninety (90) calendar days after the prior operation, or
3. In the case of a dependent, the subsequent operative procedure occurs more than ninety (90) calendar days after the prior operation and the dependent has resumed or begun normal life activities.

## **GENERAL BENEFIT EXCLUSIONS AND LIMITATIONS**

### **Important Note Regarding Relationship Between the Fund and Health Care Providers:**

No health care provider is an agent or representative of the Fund. The Fund does not control or direct the provision of health care services and/or supplies to Fund members or their covered dependents by anyone. The Fund makes no representation or guarantee of any kind concerning the quality of health care services or supplies furnished by any provider. The foregoing statement applies to any and all health care providers, including both preferred and non-preferred providers under the terms of the Plan of Benefits. The statement also applies to all entities (their agents, representatives and employees) which contract with the Fund to offer preferred provider networks or other health-related supplies to Fund members and their covered dependents. Nothing in this Plan affects the ability of a health care provider to disclose alternative treatment options to a Fund member or covered dependent. Although subject to benefit allowances and limitations in the Plan with regard to payment, the choice of a provider and/or treatment remains with the patient.

In addition to the exclusions provided elsewhere in this Booklet, benefits are not payable for the following:

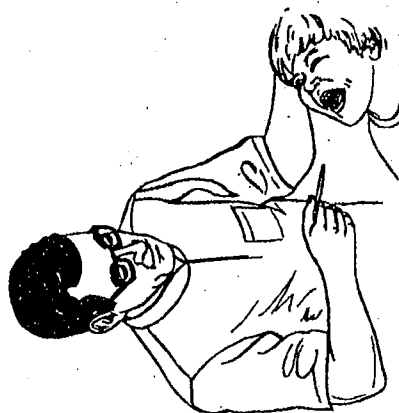
1. Charges arising from, or occurring in the course of, any gainful occupation or employment. This exclusion applies regardless of whether a claim is actually made or filed under any applicable workers' compensation statute or program.
2. Charges for services or supplies which are not medically necessary or medically appropriate as determined by the Fund and/or its Medical Consultant.
3. Charges for treatments or procedures that are experimental or investigative.
4. Charges for treatments which are not approved by the attending physician.
5. Charges which are not Usual, Customary and Reasonable.

Be advised that the Fund is your secondary carrier when an automobile accident claim arises. In other words, the Fund will only consider for payment those charges not paid under your automobile insurance policy and in certain cases only up to a certain limit. (See "Automobile Insurance" under General Provisions and Definitions.)

Keep in mind that the Fund has the right of subrogation when you are involved in any accident and where you recover any expenses which have been paid to you under this Plan from a third party.

No dental expense benefits are provided for the following:

1. Routine dental examinations performed more frequently than once in any six (6) consecutive month period.
2. Prophylaxis (cleaning of teeth) expenses in excess of the amount shown in the Summary of Benefits Schedule more often than once during any six (6) month period.
3. Dental treatments and services in connection with dentures, bridge-work, and crowns will not be covered.
  - a. If the work in making the denture, bridge or crown started prior to the effective date of coverage of the individual, or
  - b. If expenses are for more than one denture, either full or partial, or for any bridge or crown within any five year period.
4. Treatment by other than a licensed dentist, except charges for dental prophylaxis (cleaning of teeth) under the direction of a licensed dentist.
5. Orthodontic and periodontal care falling outside of the age and lifetime maximum limitations (See the Summary of Benefits Schedule for details).



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## MATERNITY COVERAGE

1. Date used to determine eligibility is the date of delivery.
2. Coverage is only for members and spouses.
3. Benefits are payable only for normal delivery, Caesarean Section or Spontaneous Miscarriages. Benefits are not payable for Therapeutic Abortion or any induced pre-term delivery, unless (a) the life of the mother is clearly threatened by carrying full term; or (b) abortion is necessary to prevent the birth of a defective or deformed fetus and has been pre-approved through the Fund office in consultation with the Fund's independent medical consultant.
4. Effective January 1, 1998, group health plans may not, under Federal law, restrict benefits for any hospital length of stay in connection with childbirth for the mother or newborn child to less than 48 hours following a normal vaginal delivery, or less than 96 hours following a cesarean section. However, Federal law does not generally prohibit the mother's or newborn's attending provider, after consulting with the mother, from discharging the mother or newborn earlier than 48 hours (or 96 hours as applicable). In any case, plans may not, under Federal law, require that a provider obtain authorization from the plan for prescribing a length of stay not in excess of 48 hours (or 96 hours). The Plan is governed by this Federal law.

## SECOND SURGICAL OPINION

A Family Member may obtain a second opinion on non-emergency surgery from another surgeon as to the necessity of any surgical operation which has been recommended. A Second Surgical Opinion will provide you with an additional medical evaluation that should help you make a more informed decision about whether you should undergo surgery or use an alternative medical treatment for a particular condition.

To encourage you to obtain a Second Surgical Opinion, the Fund will pay 100% of a the Usual, Customary and Reasonable Covered Expenses associated with obtaining the Second Surgical Opinion providing:

1. You first contact the Fund and obtain the names and addresses of several Board Certified surgeons from which you can choose to perform the second examination and give you his/her opinion, and
2. You must be examined in person by the physician rendering the second surgical opinion and a written report submitted to the Fund, and

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Schedule.

**DENTAL EXPENSE**  
**FOR MEMBERS**  
**AND DEPENDENTS**  
**EXCLUDING PARENTS**

This benefit is equal to the actual charges made by a dentist for care and treatment, but will not exceed the amount listed for each procedure in the Summary of Benefits Schedule.

This benefit is administered through both closed and open panels of dentists.

**Closed Panel:** The Fund has contracted with a panel of dentists practicing general dentistry as well as in the specialized fields of dentistry. Dentists on this panel have agreed to accept the Fund's allowance for particular dental services as payment in full with no balance billing to the patient. You will, however, be responsible for services excluded from coverage or which exceed the overall maximum benefit allowance for the patient for the plan year. A listing of panel members can be obtained, without charge, from the Fund office.

**Open Panel:** Means any dentist of your choice. However, the Fund's maximum allowance is that which is shown in the Summary of Benefits Schedule.

**BENEFITS**

The Fund has a complete "Dental Table of Allowances" - Please write the Fund if you want to know the Schedule of Allowances for any procedure not listed in the Summary of Benefits Schedule. You should contact the Fund office before you start any non-emergency work to obtain the appropriate claim forms and to insure that you are covered for benefits.

**Orthodontic Care:** Available only to your unmarried dependent children between the ages of 10 and 18 inclusive. Full cases, requiring 24 or more months of care, will be paid at the maximum benefit. Partial cases will be paid at a lesser allowance. All cases must be rated by the Fund's orthodontic consultants. The Fund maximum is shown in the Summary of Benefits Schedule. Orthodontic benefits are a life time benefit and not included in calculating the patient's yearly dental maximum.

**LIMITATIONS**

**EMERGENCY CARE:** If you have a dental emergency, you may go directly to your dentist for emergency treatment. However, the Fund will pay only for **ELIGIBLE COVERED EMERGENCY TREATMENT**.

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3. The surgeon rendering the second opinion **MUST NOT** perform the surgery if it is eventually performed. Should that occur, the fees of the physician rendering the Second Surgical Opinion will not be paid at 100%, but rather under the normal plan benefit conditions and limits (including deductibles and co-payments).

4. After obtaining a second opinion, the decision to proceed with the surgery is left entirely up to the Family Member. In other words, if the second doctor says that, in his opinion, it is not necessary to have the recommended surgery, the Family Member may nevertheless go ahead with the operation and the claim will still be honored by the Fund.

**NOTE:** As described in the "Managed Care" section which follows, the Fund may require that you obtain a Second Surgical Opinion for certain surgical procedures as a condition of providing the Fund's full Usual, Customary and Reasonable Allowance for the surgery.

**ANESTHESIA EXPENSE**

This Plan will pay a benefit for charges made by a physician who is not the operating physician or his assistant for admission of an anesthetic, which is administered in connection with a surgical procedure for which a Surgical Expense Benefit is payable under this Plan.

This benefit applies to charges made by a physician for administering an anesthetic.

The maximum amount payable for such charges in connection with a particular surgical procedure is 20% of the maximum amount paid under the Basic Surgical Expense Benefit.

**LIMITATIONS**

The combined Basic and Major Medical Surgical Benefit under this Plan will be based upon the Usual, Customary and Reasonable Allowance as determined by the Teamsters Health and Welfare Fund, subject to any deductible, co-payments or benefits maximums. Surgery performed on an outpatient basis will be paid at the Fund's Usual, Customary and Reasonable Allowance without any reduction for deductible or co-payment.

Benefits for the following surgeries will not be covered unless you contact the Fund for written approval (and approval is given) prior to undergoing any surgery:

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## VISION CARE EXPENSE

### BENEFIT (Non-Occupational)

This benefit is administered through both closed and open panels (see note below) of eye doctors. Your Vision Care Claim form can be obtained from either the Fund Office or your Local Union.

#### TYPE OF BENEFIT

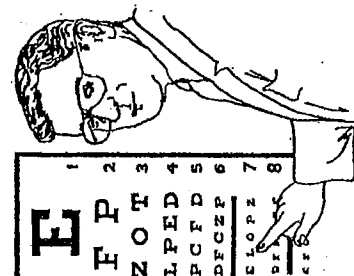
Eye Examination	<div style="font-size: 3em;">}</div>	The maximum allowances for these items are indicated in Summary of Benefits Schedule
Frames		
Lenses (Two)		
• Single Vision		
• Bifocal		
• Trifocal		
• Lenticular		

#### LIMITATIONS

Benefits are payable only as often as indicated in the Summary of Benefits Schedule. Lenticular Lenses are covered only when they are prescribed in connection with cataract surgery.

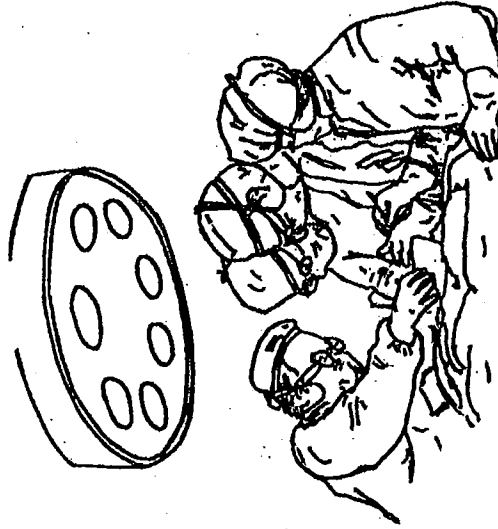
**NOTE: Closed Panel:** When you contact the Fund office for your Vision form we will send to you, without charge, a list of doctors who have agreed to accept the Fund's allowance as payment in full when particular material is selected.

**Open Panel:** Means any doctor of your choice. However, the Fund's maximum allowance is that which is shown in the Summary of Benefits



1. Involving the transplant of major body organs or bone marrow, or
  2. Generally regarded as experimental or investigational in nature, or
  3. Which involves any type of cosmetic reconstruction or augmentation.
- Some examples of surgery which the Fund does not cover in any event: Surgery related to obesity, including gastric bypass and/or intestinal bypass (unless pre-certified AND approved in advance by the Fund), lipectomy, suction lipectomy or any other surgical procedure which is simply to remove fat tissue; Reduction Mammoplasty (breast reduction) and Augmentation Mammoplasty (breast enlargement) for purely cosmetic purposes and not for reconstruction of the breast or breasts following a mastectomy. Rhinoplasty (plastic surgery on the nose) unless the result of an accident or chronic nasal obstruction. In the latter case, pre-approval from the Fund is required. If you are unsure whether a procedure is or is not covered, please contact the Member Services Department at the Fund Office.

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## FOR MEMBERS AND DEPENDENTS

### PRESCRIPTION DRUG EXPENSE

This Plan provides benefits for prescription legend drugs or refills thereof when dispensed by a pharmacy pursuant to a physician's prescription. These benefits are subject to a patient co-pay for each prescription or refill. Consult your Summary of Benefits Schedule for further details.

In addition, benefits are provided for insulin and disposable syringes to be used in administering the insulin (whether or not you have a prescription for the insulin or these disposable syringes).

### LIMITATIONS

The Fund will not pay any of the cost for:

1. Vitamins (whether legend or non-legend); cosmetics or other health and beauty aids; dietary aids; therapeutic devices and appliances; hypodermic needles and syringes (other than described above); bandages and similar supplies; support garments; and other non-prescription substances.
2. Contraceptives.
3. Administration or injection of any drug.
4. Refill of covered prescription drugs in excess of the number specified by the physician, or any refill dispensed after one year from the date of the physician's latest order.
5. Drugs otherwise provided for under the Fund's Hospital, Medical and Surgical Plan.
6. Drugs otherwise provided for under any government program or law or workmen's compensation or occupational disease laws.
7. Drugs dispensed prior to the effective date of coverage under this Plan or after the date such coverage terminates.
8. More than a 34 day supply of any covered prescription drug.
9. YOUR PHARMACY CARD IS ONLY VALID AS LONG AS YOU MAINTAIN YOUR NORMAL ELIGIBILITY. SHOULD YOU USE YOUR CARD WHEN YOU ARE INELIGIBLE, YOU WILL BE LIABLE FOR THE CHARGES.

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## MANAGED CARE PROGRAM

In an effort to ensure that benefits provided are for the highest quality of medical services rendered in the most appropriate setting (be it as an inpatient, an outpatient, in a specialty facility or at home), the Trustees of the Fund adopted a "Managed Care" program that has several parts - Pre-Admission Certification, Concurrent Stay Review, Mandatory Second Surgical Opinion, Individual Case Management and Discharge Planning.

All inpatient hospital admissions, as well as outpatient surgical procedures, are subject to the Managed Care Program of the Fund. The Fund, under its Managed Care Program, does not approve or deny an admission or continuation of inpatient hospital care for medical reasons, but does determine the amount of benefit coverage, if any, payable by the Fund for such care. To maximize your benefit coverage, you and/or your doctor must abide by the procedures of the Fund's Managed Care Program which are as follows:

### A. Pre-Admission Certification

Only inpatient or outpatient hospital care recommended by a physician as being medically necessary and appropriate will be considered.

The Fund must be notified at least three (3) days in advance of the admission so that its precertification process can be completed. If, however, an admission is made on an emergency basis, the Fund must be notified of the admission within two (2) business days after the date of admission. The Fund will contact the medical provider and either certify the admission and assign a "length of stay" or deny certification and the Fund will notify the participant and the medical provider(s) of its decision. Note: Those members covered under the Fund's Blue Cross program should call (or have their doctor call) the "800" number on the back of the Blue Cross identification card to precertify a hospital admission or hospital outpatient surgical procedure.

In the event of denial of either certification of admission or approval of the requested length of stay, the participant may appeal such decision to the Fund's Claims Review Committee pursuant to the Claims Review Procedure set forth on pages 55 to 57 in this booklet and the Fund shall render a decision on the matter in accordance with that procedure.

### B. Concurrent Stay Review

Only hospitalizations recommended by a physician as being medically necessary and appropriate to be continued beyond the date of the initial length of stay will be considered for certification.

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13. Temporary rental (six months) or purchase (whichever is less) of hospital bed, iron lung, wheelchair, apnea monitor, dextrometer or glucometer and their supplies. Other types of durable medical equipment may be covered, but require prior approval by the Fund. The Fund has established Usual, Customary and Reasonable Allowances for this type of equipment. For the specific allowance for any particular equipment, please contact the Fund's Member Services Department.

#### LIMITATIONS

Dental Care - All of the Covered Expenses listed above will apply only if such care is the result of an accidental injury and charges were not already paid under any other provision of this Plan.

The following items are subject to special allowances and/or limitations as indicated in the Summary of Benefits Schedule.

Cosmetic Surgery - See Limitations under both the Surgery Expense Benefit and the General Benefit Exclusions sections of this Booklet.

Mental or Nervous Disorders - Charges for professional psychiatric services, which shall include treatment by a clinical psychologist, for a Family Member who is not confined in a hospital as an inpatient which exceeds the per visit limit shown in the Summary of Benefits Schedule will not be considered Covered Expenses.

Special Care Facility - A benefit will be payable as indicated in the Summary of Benefits Schedule. Please refer to the General Provisions and Definitions sections of this Booklet for the definition of a Special Care Facility.

Alcoholism, Drug Abuse, Mental and Nervous Disorders Benefit - Each inpatient and outpatient service is subject to specific limitations as described in the Summary of Benefits Schedule.

NOTE: The Question and Answer section of this Booklet contains material concerning the way your Major Medical Benefits are determined.

\*\*Who is neither a member of the patients household nor a close relative.



A Managed Care representative of the Fund will contact the hospital prior to the scheduled discharge date of the patient and, after review, will either certify or deny the medical necessity of any suggested extended length of stay. If certified, a new length of stay will be assigned and, thereafter, the same procedure will be followed. Note: The Managed Care Department of Independence Blue Cross will conduct the Concurrent Stay Review for those participants covered under the Fund's Blue Cross Program.

In the event of denial of certification of the requested extended length of stay, the participant may appeal such decision to the Fund's Claims Review Committee pursuant to the Claims Review Procedure set forth on pages 56 to 58 in this booklet and the Fund shall render a decision on the matter in accordance with that procedure.

#### C. Mandatory Second Surgical Opinion

The Fund's Managed Care Program also requires a second physician's opinion prior to an inpatient or outpatient admission for certain surgical procedures. You do not have to follow the second opinion, but you must obtain it for the admission to be approved. You or your doctor can call the Fund (or Independence Blue Cross if you are covered under the Blue-Cross program) to verify whether a second opinion is mandatory for your particular case.

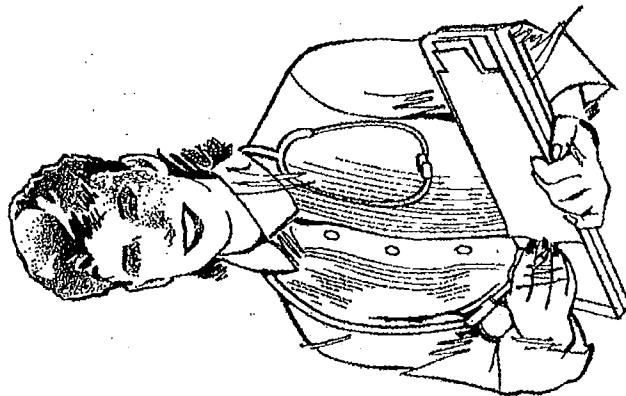
If a second opinion is required, the fees of the physician rendering the second opinion will be paid in accordance with Second Surgical Opinion benefit provisions set forth on pages 23 to 24 of this booklet.

#### D. Individual Case Management/Discharge Planning

In some instances, a patient's needs may be met as well or better by offering an alternative to acute care hospital confinement. Such plans could include home, hospice, specialty rehabilitation or skilled nursing facility care. For these reasons, the Trustees of the Fund have adopted an Individual Case Management Program which addresses these special needs in appropriate cases and provides benefit coverage not otherwise provided under the regular Plan of Benefits. In essence, these special benefits, such as hospice, skilled nursing, home infusion therapy, specialty rehabilitation care and home health care are "traded off" for the patient's available acute care hospital days. Such "trade-offs" are available only under the Case Management Program.

In appropriate cases, the patient or the patient's representative will be asked to sign an authorization form allowing the Fund and its Case Manager to explore treatment alternatives with the patient's treating

physician. Working with your physician, the Case Manager assesses whether alternative care is suitable for the individual patient. Thereafter, with your approval and that of your doctor, health care services are coordinated and carried out in a manner that ensures continuity and quality of care. The patient and/or the treating physician may refuse to continue with Case Management services. Thereafter, in that event, benefit coverage will be limited to that provided under the Fund's regular Plan of Benefits as set forth in the Summary of Benefits Schedule.



- b. Actual charges by the hospital for medical care and treatment, providing such care and treatment is necessary for the treatment of the illness/injury for which you are confined and which are normally billed by and payable to the hospital.
2. The fees of a physician.
3. Anesthetics and their administration.
4. Ambulance service for emergency local travel (a one-way trip of 150 miles or less).
5. X-ray and laboratory examinations.
6. Drugs, medicines and supplies obtainable only upon the prescription of a physician, except as provided under our prescription drug plan.
7. Artificial limbs, breast implants (if not cosmetic), eyes and larynx.  
NOTE - ONLY INITIAL PURCHASES OF THESE ITEMS ARE COVERED.
8. Assistant surgeon's fee, if medically necessary, and only if a qualified intern, resident, or other in-house physician is not available.
9. Private duty professional nursing service by a registered graduate nurse, or a licensed practical nurse.\*\* These services are limited to a maximum of 240 hours per calendar year when rendered outside the hospital.
10. Treatment by a physiotherapist.\*\*
11. Speech Therapy by a qualified speech therapist\*\* if required because:
  - a. Of an illness or a neurological disorder/dysfunction other than a functional nervous disorder, or
  - b. If to correct a congenital anomaly, the patient must have had corrective surgery before therapy will be covered, and the patient must have been eligible under this provision at the time of birth as well as the date surgery was performed.
12. Surgical dressings; blood and blood plasma; electronic heart pacemakers; casts, splints, trusses, braces and crutches; dialysis equipment; treatments by x-ray, radium or other radioactive substances; allergy testing and oxygen and other gases and the equipment for its administration.

**MAJOR MEDICAL EXPENSE**FOR MEMBERS  
AND DEPENDENTS

For those enrolled in the Fund's "Traditional" benefit program, this Plan will pay Major Medical Expense Benefits for Covered Expenses (as described on the following pages) incurred in connection with a non-occupational disease or injury, and which have been prescribed by a physician and which are medically necessary or appropriate. All such allowances shall be up to the Usual, Customary and Reasonable amount as determined by the Fund. Not all plans have Major Medical coverage. Please refer to the Summary of Benefits Schedule. For those enrolled in either the *Personal Choice™* or *Keystone HMO™* Programs, please refer to your Member Handbook for benefit coverage descriptions.

**BENEFITS**

This benefit will be payable for a Family Member's Covered Expenses incurred in any calendar year, if that Family Member's expenses exceed the sum of:

1. The basic covered expense benefits, as described elsewhere in this Booklet, and
2. The deductible shown in the Summary of Benefits Schedule.

The amount of benefits payable for the excess covered expenses in excess of the basic benefit and applicable deductible and the amount of the maximum, major medical benefits are shown in the Summary of Benefits Schedule.

Covered expenses are the hospital expenses and other expenses listed below, if such expenses are incurred while Major Medical coverage is in force for the Family Member. However, listed expenses incurred in connection with mental or nervous disorders, dental work or oral surgery will be considered Covered Expenses only to the extent of the maximums described in the Summary of Benefits Schedule.

Furthermore, if any of the listed expenses are excluded from coverage because of a reason described in the General Benefit Exclusions section of the Booklet, those expenses will not be considered Covered Expenses.

**COVERED EXPENSES**

1. The following hospital bills:
  - a. Hospital Room and Board not to exceed the hospital's average semiprivate room charge per day, and

FOR MEMBERS  
AND DEPENDENTS**OUTPATIENT DIAGNOSTIC  
LABORATORY AND  
X-RAY EXPENSE****BENEFITS  
(Non-Occupational)**

This benefit applies to the actual charges made for each laboratory or x-ray examination made solely for diagnosis of a disease or injury. The maximum amount payable for all examinations made in connection with all diseases during one calendar year is the laboratory and x-ray maximum shown in the Summary of Benefits Schedule. Depending upon the actual Plan under which you are covered, balances remaining after Basic Benefits have been exhausted for outpatient diagnostic, laboratory and/or x-ray charges may be payable under the Major Medical program. Consult your Summary of Benefits Schedule to determine your coverage.

**LIMITATIONS**

This benefit will only be payable if benefits are not payable under the Hospital Expense Benefit.

Claim date is the date service is rendered.

The Fund has established Usual, Customary and Reasonable Allowances for outpatient x-ray technical and professional services. These allowances serve as the maximum allowed for any given procedure (before reduction for any applicable deductible or co-payment).

**OUTPATIENT X-RAY AND LABORATORY  
PREFERRED PROVIDER ORGANIZATION**

If your doctor suggests that you have an x-ray or other radiologic examination or test done as an outpatient, you can avoid deductibles and co-payments by using the Fund's Outpatient X-Ray PPO. The participating diagnostic centers have agreed to accept the Fund's allowance as payment in full with no balance billing to you. Furthermore, no deductible or co-payment applies if you have the test done through one of the participating centers.

The X-Ray and Laboratory PPO program is administered by Health Care Solutions. You can call HCS to verify your eligibility, obtain a referral number and locate the participating center most convenient for you. For more information regarding this program, contact the Fund's Member Services Department.

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### OUTPATIENT EMERGENCY ACCIDENT EXPENSE

FOR MEMBERS  
AND DEPENDENTS

This Plan will pay an Accident Expense Benefit for Covered Expenses incurred in connection with a non-occupational accidental bodily injury.

#### BENEFITS

If a Family Member sustains an accidental bodily injury, (as defined in this booklet) a benefit will be paid for the treatment, providing;

Treatment is received in the office of a legally qualified physician or in a lawfully operated hospital, and

Treatment is received within 72 hours of the accident.

If the above conditions are met, any follow-up treatments relating to the same accident will also be covered under this benefit, providing you remain eligible.

The benefit applies to actual charges, but not exceeding the amount set forth in the Summary of Benefits Schedule.

#### LIMITATIONS

1. Be advised that the Fund is your secondary carrier when an automobile accident claim arises. In other words, the Fund will only consider for payment those charges not paid under your automobile insurance policy and in certain cases only up to a certain limit. (See "Automobile Insurance" under General Provisions and Definitions.)
2. Keep in mind that the Fund has the right of subrogation when you are involved in any accident. Please refer to the section related to Subrogation of Benefits found on page 50 of this Booklet.
3. Except for certain circumstances for those members covered under the Fund's Blue Cross program, charges for emergency treatment of any illness, such as a sore throat, a high fever, a pain in the chest or the flu are not covered under this benefit. Consult your Summary of Benefits Schedule for further details.

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FOR MEMBERS  
AND DEPENDENTS

### OUTPATIENT RADIATION CHEMOTHERAPY EXPENSE

This Plan will pay a Radiation/Chemotherapy Expense Benefit when rendered by a physician for a proven condition (either malignant or non-malignant) caused solely by a non-occupational disease or injury.

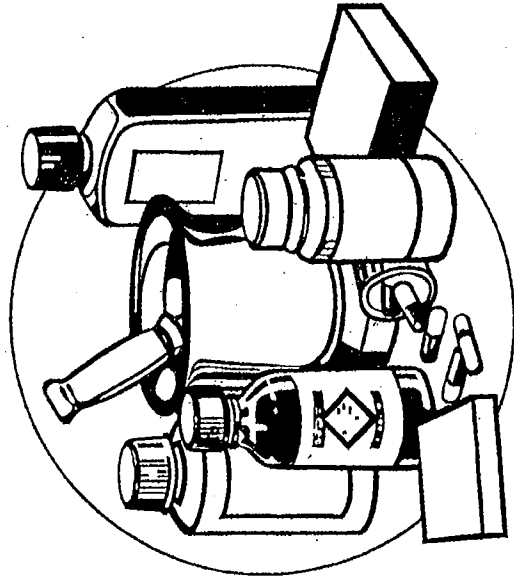
#### BENEFIT

The maximum benefit is the allowance shown in the Summary of Benefits Schedule.

The benefit covers expenses for radiological, radon, radium, radioactive isotope therapy or chemotherapy. The claim date is the date the service is rendered.

#### IMPORTANT!!

Patients receiving this type of therapy could greatly benefit from the Fund's Case Management Program or the Fund's Preferred Provider Organization. You should contact the Fund's on-staff Case Management Coordinator in the Member Services Department or the Managed Care Department at Independence Blue Cross.



# **Exhibit 22D**

July 4, 2000

**SUMMARY OF BENEFITS SCHEDULE**

Contribution Rate:  
\$25.98/\$25.94

Benefits are effective 60 days after effective date of rate.

THWF0147

**TEAMSTERS HEALTH & WELFARE FUND  
OF PHILADELPHIA AND VICINITY**

Fourth and Cherry Streets  
Philadelphia, PA 19106  
(215) 923-6300

**NATIONWIDE WATS LINE**  
1-800-523-2846

**PLAN SPONSOR**

Board of Trustees of the Teamsters Health & Welfare Fund  
of Philadelphia and Vicinity  
Fourth and Cherry Streets  
Philadelphia, PA 19106

**BOARD OF TRUSTEES**

The Board of Trustees represents labor and management and  
are responsible for governing the entire operation of the Fund.

**LABOR TRUSTEES**

Paul Cardullo, President  
I.B.T. Local 929  
4345 Frankford Avenue  
Philadelphia, PA 19124

Thomas P. Hummel, President  
I.B.T. Local 470  
3665 Sepviva Street  
Philadelphia, PA 19134

Frank Gillen, Internat'l Trustee  
I.B.T. Local 407  
107 Spring Garden Street  
Philadelphia, PA 19123

**MANAGEMENT TRUSTEES**

Arnold S. Rosenthal  
9752 Morefield Road  
Philadelphia, PA 19115

Kenneth F. Leedy, President/CEO  
New Penn Motor Express  
625 South Fifth Avenue  
Lebanon, PA 17042

Bob Schaeffer, Executive Director  
Transport Employers Association  
One Lafayette Place, Suite 200  
Lafayette & Swede Streets  
Norristown, PA 19401



**ADMINISTRATOR AND AGENT FOR SERVICE OF LEGAL PROCESS**  
(Legal process may also be served upon a Trustee)

William J. Elmhorn  
Fourth & Cherry Streets  
Philadelphia, PA 19106  
(215) 923-6300

**LEGAL COUNSEL**

Schnader, Harrison Segal & Lewis, LLP  
Suite 3600, 1600 Market Street  
Philadelphia, PA 19103  
Freedman & Lory, P.C.  
400 Market Street, Suite 900  
Philadelphia, PA 19106

**AUDITOR**

Ernst & Young, LLP, conducts  
periodic audits of the Fund.  
Two Commerce Square, Suite 400  
2001 Market Street  
Philadelphia, PA 19103  
(215) 448-5000

**PRESCRIPTION DRUG PROGRAM**

General Prescription Program, Inc.  
127 East 59th Street  
New York, NY 10022

**INVESTMENT MANAGER**

SEI Investments  
One Freedom Valley Drive  
Oaks, PA 19456

The Health & Welfare Fund Covers Employees  
Represented by these Teamsters Locals

Local 107  
Local 415  
Local 169  
Local 312  
Local 326  
Local 331  
Local 384  
Local 470  
Local 500  
Local 623  
Local 628  
Local 676  
Local 929

THWF0148

The only person authorized to advise you of your rights under this Plan is  
William J. Elmhorn, Administrator of this specific designee.

Reliance upon information from any other source is at your own risk.

Prescription Drugs, Vision and Dental Benefits are not subject to the Major Medical Provisions.

**SCHEDULE OF SURGICAL BENEFITS**

In the past, when the Fund listed certain benefit amounts for specific surgeries, misunderstandings have sometimes occurred. Often there are several different kinds of surgery which can be performed for the same illness. So, in some cases, the patient relied on the list which the Fund had published for payment when, in fact, the surgeon performed a less difficult surgery and received an amount less than the patient anticipated.

In the future, should you wish to inquire as to the amount of the Fund's allowance for a particular surgery, we suggest that you have your surgeon send us a preoperative report along with a letter stating his fee and appropriate CPT-4 Code for the surgery which he intends to perform. This will enable us to respond to you with an accurate allowance amount.

Incidentally, in cases where you have time to inquire about the Fund's allowance, it would also be wise to avail yourself of the Fund's Second Opinion Surgery Benefit.

**NOTE: Please read Surgical Limitations on page 20 of the Benefit Booklet.**

**ELIGIBILITY**

A member of the Teamsters Health and Welfare Fund of Philadelphia and Vicinity will become and remain eligible for the Benefit Program in accordance with the following "Qualifying Schedule."

**QUALIFYING SCHEDULE**

If an Employer is required to make contributions to the Fund on behalf of a member for at least:

15 days during the month of OR 180 days during the months of Such member will be eligible for benefits during the month of

November	December through November	January
December	January through December	February
January	February through January	March
February	March through February	April
March	April through March	May
April	May through April	June
May	June through May	July
June	July through June	August
July	August through July	September
August	September through August	October
September	October through September	November
October	November through October	December

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**DEPENDENT ELIGIBILITY**

Eligibility for benefits for each of your dependents will be determined on the same basis as for you, except where noted:

**NOTE:** Even if you are not eligible using the above schedule, you may still be eligible -- see the Extension of Benefits section of your Benefit Booklet.

**MAJOR MEDICAL EXPENSES/BENEFITS**

This benefit will be payable for a family member's covered medical expense incurred in any calendar year if that family member's expenses exceed the sum of:

1. The Basic Medical Expense Benefits, as described in your Benefit Book and elsewhere in this Summary of Benefits Schedule, and
2. The deductible described below.

The deductible is the first \$100.00 of eligible expenses incurred by the family member during the calendar year. Any deductible satisfied during October, November and December is also carried over to the following year. However, all family members collectively need only satisfy a \$200.00 deductible during a calendar year, and each individual will be considered as having satisfied their deductible for that year.

The benefit will pay 75% of the family member's covered charges until that family member's out-of-pocket expense reaches \$825.00. The Fund will then pay 100% of all covered charges until you reach your per illness and/or lifetime limit.

The eligible expenses include dental, customary and reasonable hospital bills, surgery, doctor's service, private nursing, medicine, x-rays and many other items. Additionally, hospital outpatient charges for emergency medical treatment, kidney dialysis, physical therapy, occupational therapy, respiratory therapy and cardiac rehabilitation therapy that are provided in a Blue Cross member hospital are covered in full under your Basic Benefit coverage. If these services are rendered outside a hospital setting, they are covered only under your Major Medical coverage. Please consult your Benefit Book for full details.

In-hospital doctor visits shall be paid at 75% of covered charges and are not subject to the \$100.00 deductible.

**LIMITATIONS**

1. Room and board is covered only up to the hospital's average semi-private room charge.
2. Mental and Nervous Disorders Outpatient Benefit -- 75% of covered professional charges. The maximum allowance per visit will not exceed \$75.00. Yearly maximum is 30 visits. This benefit is not subject to the \$100-deductible.
3. Special Care Facility -- Charges not exceeding \$80.00 per day (inpatient) up to a maximum of \$3,000.00 each calendar year. (This limitation does not apply to treatment for mental and nervous disorders.)

**MAXIMUM MAJOR MEDICAL PAYMENT (For Each Family Member):**

Sickness.....\$250,000.00  
Lifeline.....\$1,000,000.00

**Automatic Reinstatement** -- On the first day of each year, each covered individual who has had benefits charged to his overall maximum will automatically have an amount reinstated for future use. The amount to be reinstated each year will be \$1,000.00 or the amount needed to bring the maximum back to the full amount, whichever is less.



## BENEFITS

## DEATH BENEFITS

Member.....	\$20,000.00
Death Benefit continued in force on member in the event of total disability.....	\$3,000.00
Spouse.....	\$1,500.00
Child - In accordance with age as follows:	
Over 14 days, but less than six months.....	\$300.00
Six months, but less than two years.....	\$600.00
Two years, but less than three years.....	\$1,200.00
Three years, but less than 19 years (23 years if in full-time attendance at an accredited secondary school, college or university) or a child over 19 who has a mental or physical disability as described in your Benefit Book.....	\$1,500.00

## ACCIDENTAL DEATH AND DISMEMBERMENT BENEFIT

Member - Principal Sum.....	\$20,000.00
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## WEEKLY DISABILITY (Loss of Time) BENEFIT - Member Only

Per Week.....	\$250.00
Per Work Day.....	\$50.00

NOTE: If you work for a company that contributes \$25.94 per day to the Fund, you will receive a benefit equal to 1/2 of the disability payment indicated above.

## Commencement of Benefit:

Accident or from first day of hospitalization.....	First Work Day
Sickness or pregnancy.....	Sixth Work Day
Maximum period payable.....	26 Weeks

## PRESCRIPTION DRUGS (Cash Deductibles Per Prescription)

Generic Drugs.....	\$3.00
Brand Name Drugs.....	\$9.00

## VISION BENEFITS

This benefit is administered through both closed and open panels of eye doctors. Benefits are payable only if you are eligible at the time the vision service is performed. The Vision Care Benefits are as follows:

Eye Examination (one every 24 months).....	\$30.00
Frames (one pair every 24 months).....	\$22.00
Lenses (one pair every 24 months).....	\$28.00
Single Vision.....	\$32.00
Bifocal.....	\$37.00
Trifocal.....	\$110.00
Lenticular.....	

NOTE: The closed panel doctors will ordinarily accept the Fund's allowances as payment in full. A list of these doctors may be obtained from the Fund office.

## SECOND MEDICAL OPINION ON NON-EMERGENCY SURGERY

A family member may obtain a second opinion on non-emergency surgery from another surgeon as to the necessity of any surgical operation which has been recommended.

The Fund will bear the entire usual, customary and reasonable cost of obtaining this second opinion, provided:

1. You first contact the Fund and obtain the name of a Board Certified surgeon to perform the second examination and give you his opinion, and
2. You must be examined in person by the physician rendering the second surgical opinion and a written report must be submitted to the Fund; and
3. The surgeon rendering the second opinion must not perform the surgery if it is eventually performed.

After obtaining a second opinion, the decision to proceed with the surgery is left entirely to the family member. In other words, if the second doctor says that, in his opinion, it is not necessary to have the recommended surgery, the family member may, nevertheless, go ahead with the operation and the claim will still be honored by the Fund.

## ANESTHESIA CHARGES

The maximum amount payable for such anesthesia charges in connection with a particular surgical procedure is 20% of the Fund's Basic surgical allowance for that same surgical procedure.

## DIAGNOSTIC LABORATORY AND X-RAY BENEFITS

Maximum payment in any calendar year.....	\$200.00*
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## OUTPATIENT EMERGENCY ACCIDENT

Maximum payment for treatment received within 72 hours.....	\$300.00*
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## RADIATION/CHEMOTHERAPY EXPENSE BENEFIT

Maximum payment in any calendar year.....	\$300.00*
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\*When these services are provided by a Blue Cross member hospital in an outpatient setting, the hospital charges are covered in full under your Basic Benefit coverage. Services rendered by physicians or outside of a hospital setting are subject to the yearly Basic Benefit maximums shown above.

## ALCOHOLISM &amp; DRUG ABUSE COVERAGE (INPATIENT/OUTPATIENT)

Services are subject to a single and combined Basic and Major Medical lifetime benefit.....	\$5,000.00.
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## MENTAL &amp; NERVOUS DISORDERS (INPATIENT)

Maximum lifetime confinement days.....	25 days
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**DENTAL EXPENSE BENEFITS**

This benefit is administered through both closed and open panels of dentists. Benefits are payable only if you are eligible at the time each procedure is performed.

Family Member Calendar Year Maximum..... \$1,500.00

(This maximum does not include any orthodontia payments)

Orthodontia - Family Member Lifetime Maximum..... \$1,800.00

(Available only for dependent children between the ages of 10 and 18, inclusive.)  
NOTE: The closed panel dentists will ordinarily accept the Fund's allowances as payment in full. A list of these doctors may be obtained from the Fund office.

**SCHEDULE OF DENTAL BENEFITS**

The maximum allowances may not exceed the fee actually charged for the procedure. No payment will be made until the required Dental Claim Form has been completed by the attending dentist and approved by the Fund. This Table of Allowances will apply to all. For any procedure which has an allowance that is different from Members or Dependents over the age of 14 and for Dependent Children between the ages of 0 and 14, the description indicates "adult" or "child."

The following is only a PARTIAL listing of covered procedures. A complete listing may be obtained at the Fund office.

ADA Code #	PREVENTIVE	Maximum Allowance
01110	Dental Prophylaxis - Adult .....	\$40.00
01120	Dental Prophylaxis - Child .....	\$35.00
01200	Fluoride Treatments - Child .....	\$20.00
01510	Space Maintainers - Fixed Band Type - Child .....	\$100.00

**RESTORATIVE**

ADA Code #	RESTORATIVE	Maximum Allowance
02140	Amalgam Restorations including Polishing	\$35.00
02150	Amalgam - 1 Surface - Permanent .....	\$40.00
02160	Amalgam - 2 Surfaces - Permanent .....	\$45.00
02161	Amalgam - 3 Surfaces - Permanent .....	\$50.00
02210	Amalgam - 4 Surfaces or More - Permanent .....	\$35.00
02330	Silicate Restorations	\$35.00
02331	Silicate Cement - Per Restoration .....	\$35.00
02332	Acrylic Plastic or Composite Restorations	\$40.00
02335	Composite/Bonding 1 Surface .....	\$45.00
02750	Composite/Bonding 2 Surfaces .....	\$50.00
02791	Composite/Bonding 3 Surfaces .....	\$325.00
02931	Composite/Bonding 4 Surfaces .....	\$225.00
	Crowns - Single Restorations Only	\$75.00
	Porcelain with Metal (Ceramco) .....	
	Gold - Full Cast Crown - Molar .....	
	Stainless Steel Crown .....	

Those members who are enrolled in the Fund's Personal Choice and Keystone HMO Benefit programs should refer to the separate Member Handbook that was mailed to them by independent Blue Cross. These booklets explain the medical, hospital and surgical programs under which you would enjoy coverage. If you did not receive a copy and are enrolled in one of these programs, contact the Teamsters' Dedicated Service Unit at Blue Cross (1-800-354-8283).

For those covered under the Fund's Traditional Benefit Program, your Hospital, Medical and Surgical Benefits are as follows:

**HOSPITAL EXPENSE (See definition of hospital in Benefit Book)**

Hospital benefits under this program are administered through Independence Blue Cross. Hospital admissions and outpatient surgery require Pre-Admission Certification. You or your doctor should call 1-800-732-7825 prior to services. Emergency admissions require review within one working day after admission.

**Room and Board**

Commencement of benefit..... 1st Day in Hospital  
Maximum period during any disability or illness..... 365 Days  
Maximum daily benefit..... Full Average Semi-Private  
Miscellaneous Services..... Full Usual, Customary and Reasonable  
Ambulance Service Expense..... \$25.00

NOTE: If you have additional hospitalization coverage (other than Blue Cross) for which you pay the entire premium, that coverage shall always pay its benefits first. The Fund's hospitalization coverage shall then pay to you the lesser of the Fund's normal allowance for the hospital stay or an amount equal to \$600.00 times the number of days hospitalized as indicated on the hospital bill.

**PRE-ADMISSION TESTING**

(You May Be Able to Shorten Your Hospital Stay)

Whenever it appears that it will be necessary for the hospital to administer tests prior to surgery or to confirm a diagnosis, you may have these tests done on an outpatient basis and the Fund will pay them under the Independent Hospitalization Allowance. In order to be eligible for this benefit, the tests must be performed within one week of the scheduled hospital admission and must not be of a type which are routinely repeated upon admission prior to surgery.

**SURGICAL CHARGES**

The doctor fees for covered surgical procedures will be paid up to the limit indicated below:

Maximum Basic payment for all surgical procedures due to the same or related cause up to..... \$1,800.00

NOTE: Please read Surgical Limitations on page 20 of the Benefit Booklet

The combined Basic and Major Medical Surgical Benefit under this Plan will be based upon the Usual, Customary and Reasonable allowance as determined by the Teamsters Health and Welfare Fund, subject to any deductibles, copayments or maximums.

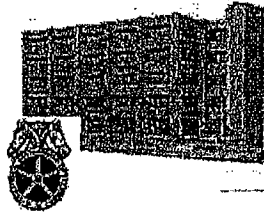
ADA Code #	ENDODONTICS	Maximum Allowance	PROSTHODONTICS, FIXED	
			(For Fixed Bridges, Each Abutment and Each Pontic Constitutes a Unit and a Bridge)	
03110	Pulpotomy (Excluding Final Restoration) Pulp Cap -- Direct.....	\$11.00	Bridge Pontics -- reimbursement for pontics will be handled in the same manner as 1 and 2 below.	
	Root Canal Therapy -- Includes Clinical Procedures and Follow-up Care		Pontic -- Porcelain Fused to Metal**.....	\$325.00
03310	Endo -- 1 Canal -- Excludes Restoration	\$200.00	Pontic -- Porcelain Fused to Metal**.....	\$250.00
03320	Endo -- 2 Canals -- Excludes Restoration	\$225.00	Pontic -- Plastic Processed to Metal**.....	\$250.00
03330	Endo -- 3 Canals -- Excludes Restoration	\$325.00	Pontic -- Plastic Processed to Metal**.....	\$250.00
03340	Endo -- 4 Canals -- Excludes Restoration	\$400.00	Crown.....	
			Plastic Processed to Metal**.....	\$225.00
			Porcelain Fused to Metal**.....	\$300.00
			Gold Full Cast -- Any Tooth.....	\$265.00
			Other Services	
04220	Non-Surgical Services Gingival Curettage.....	\$35.00	Recent Bridge.....	\$25.00
04210	Surgical Services Gingivectomy or Gingivoplasty -- Per Quadrant.....	\$75.00		
04260	Osseous Surgery -- Includes Flap Entry, Closure -- Per Quadrant.....	\$150.00		
04340	Adjunctive Services (Performed by Periodontal Specialist)			
04341	Periodontal Scaling & Root Planning (Full Mouth) Periodontal Scaling & Root Planning (Fewer than 12 Teeth).....	\$90.00 \$50.00		
			ORAL SURGERY	
			Simple Extraction -- Includes Local Anesthesia and Post Operative Care	
05110	Complete Dentures Upper Dentures -- Adult.....	\$350.00	Extraction -- Single Tooth.....	\$40.00
05120	Lower Dentures -- Adult.....	\$350.00	Each Additional Tooth.....	\$40.00
05320	Additional Unit for Partial Dentures First Additional Clasp.....	\$15.00	Surgical Extraction -- Includes Local Anesthesia and Post Operative Care	
05730	Denture Relining Reline -- Upper or Lower Complete Denture -- Office Reline.....	\$45.00	Surgical Extraction of Teeth -- Erupted.....	\$40.00
05750	Reline -- Complete Denture -- Laboratory	\$75.00	Extraction of Tooth -- Complete Bone -- First Teeth	\$449.00
			Other Surgical Procedures Applied to Teeth	
			Alveoplasty -- with Extractions.....	\$50.00
			Alveoplasty -- Surgical Preparation of Ridge for Dentures	
			Alveoplasty -- One Arch -- Edentulous.....	\$65.00
			OTHER SERVICES	
			Unclassified Treatments General Anesthesia.....	\$80.00

THWF0152

# **Exhibit 22E**

Keystone - PA (01K)

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**Teamsters**  
Health & Welfare and Pension Funds  
of Philadelphia and Vicinity

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**Keystone - PA**

MEDICAL COVERAGE: (Effective 01/01/2003)

YOUR PRIMARY CARE PHYSICIAN MUST COORDINATE ALL SERVICES

ALL SERVICES MUST BE DONE BY AN IN-NETWORK PROVIDER

IF YOU RECEIVE SERVICES WITHOUT OBTAINING A REFERRAL,  
YOU WILL BE RESPONSIBLE FOR PAYMENT

BENEFIT DESCRIPTION	IN-NETWORK	OUT-OF-NETWORK
<b>Deductibles</b>		
Individual	\$0	No Coverage
Family	\$0	No Coverage
Co-insurance	Not applicable (N/A)	No Coverage
Out-of-Pocket	N/A	No Coverage
Annual Copay Maximum	\$440 per person	No Coverage
<b>Limits</b>		
Lifetime Maximum	\$2 million	No Coverage
Hospital Days	Unlimited	None
Hospital Outpatient	Covered 100%	No Coverage
Inpatient Psychiatric Days	30 days per year	None
Lifetime Psychiatric Max	N/A	No Coverage
Lifetime Alcohol/Substance Max	120 outpatient visits/90 inpatient days	No Coverage
<b>Office Visits</b>		
Primary	100% - \$5 per visit copay After hours care has \$10 per visit copay	No Coverage
Specialists	100% w/Primary Physician Referral \$10 per visit copay	No Coverage
Preventative Care	100% with \$5 copay	No Coverage
Pediatric Immunization	100% with \$5 copay	No Coverage
Outpatient Therapies	100% up to 60 consecutive days per condition	No Coverage
<b>Outpatient Psychiatric</b>		
Visits 1 - 2	Covered 100%	No Coverage
Visits 3 - 30	\$25 copay per visit or 50% of allowable charge	No Coverage

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Keystone - PA (01K)

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	(whichever is less)	
Maximum Visits Per Year	30	No Coverage
Alcohol/Substance Abuse		
Inpatient	30 days per year - 100%	No Coverage
Outpatient	60 visits per year - 100% w/\$5 copay per visit	No Coverage
Other Services		
Emergency Room (life-threatening emergency illness or injury; copay waived if admitted)	Covered with a \$40 copay	Covered with a \$40 copay
Anesthesia and Surgical	Covered 100%	No Coverage
Maternity	Covered 100%	No Coverage
Maternity Specialist	100% - \$10 per visit copay for routine care	No Coverage
Lab, X-ray, and Diagnostic	Covered 100%	No Coverage
Gynecological Care	100% - (2 visits per year w/o referral - \$10 copay)	No Coverage
Home Health and Hospice	Covered 100% with authorization	No Coverage
Skilled Nursing	Covered 100% with authorization	No Coverage
Durable Medical Equipment	100% with approval	No Coverage
Allergy Testing	100% with \$5 copay per visit	No Coverage

ADDITIONAL BENEFITS	COVERAGE
Death Benefit	
Member	\$20,000.00
Accidental Death and Dismemberment - Principal Sum	\$20,000.00
Total Disability	\$3,000.00
Spouse	\$1,500.00
Dependent Child - In accordance with age as follows:	
Over 14 days, but less than 6 months	\$300.00
6 months, but less than 2 years	\$600.00
2 years, but less than 3 years	\$1,200.00
3 years, but less than 19 years (23 years if in full-time attendance at an accredited secondary school, college or university)	\$1,500.00
Over 19 if dependent has a mental or physical disability as described in your Benefit Book	\$1,500.00
Weekly Disability Benefits - Member Only	
Per Week	\$250.00

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Keystone - PA (01K)

Page 3 of 3

Per Work Day	\$50.00
<b>Commencement of Benefit:</b>	
Accident or from first day of hospitalization	First Work Day
Sickness or pregnancy	Sixth Work Day
Maximum period payable	Twenty-Six Weeks
<b>Prescription Drugs (Cash Deductible Per Prescription)</b>	
Generic Drugs	\$3.00
Brand Name Drugs (Preferred)*	\$10.00
Brand Name Drugs (Non-Preferred)*	\$20.00
* Note: Newly released drugs may require pre-certification	
<b>Vision Benefits</b>	
Eye Examinations (one every 24 months)	\$30.00
Frames (one pair every 24 months)	\$22.00
Lenses (one pair ever 24 months)	
Single Vision Lenses	\$28.00
Bifocal Vision Lenses	\$32.00
Trifocal Vision Lenses	\$37.00
Lenticular Vision Lenses (prescribed in connection with cataract surgery)	\$110.00
<b>Dental Benefits</b>	
Family member per calendar year maximum	\$1,500.00
Orthodontia - lifetime maximum (Dependent Children between the ages of 10 and 18 inclusive)	\$2,300.00

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Last Date Updated : 01/28/03

THWF0183

# **Exhibit 22F**



**GENERAL PRESCRIPTION PROGRAMS, INC.**

**5th Floor**

**61 FREEMAN STREET**

**NEWARK, NEW JERSEY 07105**

**-----  
(973) 589 - 5000**

November 14, 2003

William Einhorn, Administrator  
Teamsters Health and Welfare Fund  
of Philadelphia and Vicinity  
4th and Cherry Streets  
Philadelphia, Pennsylvania 19106-1899

Dear Bill:

Enclosed is the copy of the Agreement.

In order to reflect the actual operation presently in place, we have made slight alterations to the Agreement.

Additions to the Agreement have been italicized and deletions have been underlined.

Comments on each change are as follows:

First paragraph

General Prescription Programs, Inc. is a Delaware corporation and not a New Jersey corporation.

Section 2. Duties and Responsibilities

a. In General

i.

6. Since we have been providing service to your Fund, the plan has operated in the manner which is indicated in the italicized insertion.

Now that your Fund has a differentiation between brand and generic drugs, you may wish to continue as you have in the past. The copayment differentiation may actually be superior to anything else in motivating people to use generic drugs. The reason for this can best be seen in the following example:

The physician prescribes for a member Lopid 600 mg (AWP \$ 1.72 per tablet). The physician also indicates that the drug must be dispensed as written. The member goes to his pharmacy. The

pharmacist indicates that the member's program only reimburses for generic drugs. The member then must pay the difference between the generic Lopid 600 mg (GPP MAC \$ .32 per tablet) and the brand name Lopid. Since the physician insisted on the brand name drug, the physician should be contacted. In many instances if the pharmacist is unable to reach the physician or if the physician does not like to be bothered with telephone calls, then when the pharmacist does reach the physician, or next time the member goes to the physician, in order to avoid a hassle, the physician may prescribe a drug such as Tricor 160 mg (AWP \$ 3.19 per tablet). This drug is in a similar therapeutic class as Lopid except it is under patent protection, and as such it would cost the Fund far more money.

8. An exclusive toll free number was not in effect in the past and there were never any service issues in this regard.

## Section 2. Duties and Responsibilities

### b. Reimbursement

- ii. In the past, our mandate has been that every pharmacy in Pennsylvania and throughout the United States be available to the membership. For the most part, dispensing fees are \$2.25 or lower. The one main exception is CVS pharmacies which will not accept a lower dispensing fee. In our opinion, they should not be part of the program.

Our policy, unlike our competitors, is to never have a "spread" or "markup" at any of the retail pharmacies. Exactly the amount we are charged is exactly the amount the Fund is billed. We negotiate with the pharmacies to provide the Fund with the greatest discounts. As such, many pharmacies have lower dispensing fees than \$2.25 which is passed on to the Fund.

## Section 3. Cost of Prescriptions to the Fund (the "cost")

As we indicated above, our policy, unlike our competitors, is to never have a "spread" or "markup" at any of the retail pharmacies. Exactly the amount we are charged is exactly the amount the Fund is billed. We negotiate with the pharmacies to provide the Fund with the greatest discounts. This is extremely important. If the Fund elects to utilize those pharmacies where we have negotiated guaranteed discounts of AWP less 16% on brand name drugs, discounts of close to AWP less 18% could be achieved. The reason for this is that we reimburse the pharmacies the lower of the submitted price or our negotiated reimbursement rate, whichever is lower. It has been our experience that this reduces overall ingredient cost by close to 2%.

Many of our competitors "play games" with pharmacy discounts by establishing a strategic alliances with certain chains and co-promoting brand name pharmaceuticals. We do not do this. Therefore, any discounts that we achieve

for the Fund is a "true" discount.

Since the Fund wishes to utilize every pharmacy in the United States, as opposed to our guaranteed best discount pharmacies, we believe that the new insertion would reflect the plan more accurately.

4. Administrative costs and fees

iii. Postage

As we have indicated in the past, we believe very strongly that mail order increases the cost of a prescription drug program. At present, the program does not utilize mail order service; however, if they did wish to utilize that service, we have indicated that the actual US Postal Service/United Parcel Service/Airborne Express would be charged.

8. Utilization reports

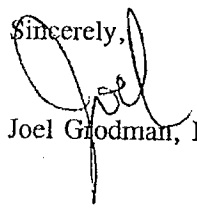
- a. As the Fund is aware, we are providing any necessary reports in any requested media to the Fund. Since we would do this for the Fund at any time indicated, we changed it to a mutually agreed time interval as opposed to a fixed time interval.

13. Term

- a. This Agreement may be terminated at any time with or without cause, as indicated in b. of this section, prior or subsequent to the expiration of the biannual period of the Agreement. This would provide the necessary flexibility to the Fund if there is to be a transition period to a new company. More specifically, the members would be protected with full coverage and these services would continue uninterrupted. The continuation of these services would be pursuant to the ongoing Agreement and there would not be undue pressure and hast to enter into a final and binding Agreement with a new pharmacy benefit company. This give the Fund added flexibility.

If there are any questions in regard to this, please do not hesitate to contact me.

Sincerely,

  
Joel Grodman, RP

THWF 1851

### PREScription DRUG SERVICES PROVIDER AGREEMENT

AGREEMENT made this 31st day of January 2003, by and among the Teamsters Health and Welfare Fund of Philadelphia and Vicinity, with offices at 4th & Cherry Streets, Philadelphia, Pennsylvania 19106 (the "Fund") and General Prescription Programs, Inc. a Delaware corporation with its principal offices at 61 Freeman Street, 5th Floor, Newark, New Jersey 07105 ("GPP").

WHEREAS, the Fund desires to provide certain prescription drug services for its eligible participants and their beneficiaries (hereinafter referred to as Participants);

WHEREAS, GPP is engaged in the business of performing certain administrative services in connection with the administration of prescription drug plans; and

WHEREAS, the Fund originally entered into an Agreement in 1986 with GPP to administer a high quality prescription drug program in a competent and efficient manner and at a reasonable price, and the Fund and GPP desire to continue the relationship on the terms and conditions set forth herein;

NOW THEREFORE, the parties hereto, in consideration of the mutual promises and duties set forth, each intending to be legally bound, do agree as follows:

1. APPOINTMENT

- a. GPP is hereby reappointed as the Pharmacy Benefit Manager of the Prescription Drug Program ("the Program") and GPP accepts such appointment.

2. DUTIES AND RESPONSIBILITIES

a. In General

- i. GPP shall provide the following administrative services for eligible Participants:

- 1. Arrange for a network of pharmacies in the United States *which who* will accept the Fund's identification card (a "Prescription Card") as payment for prescription drugs to eligible Participants;
- 2. Pay to the participating pharmacies the amounts properly due and owing;
- 3. Develop and maintain an on-line eligibility system whereby participating pharmacies have a network computer link to GPP's eligibility files. GPP shall be responsible for updating the eligibility information within twenty-four (24) hours of the transmission of same from the Fund, except for weekends and official federal and state holidays in New Jersey, in which case the twenty-four (24) hour period shall run from the beginning of the next business day following the weekend or official federal or state holiday. Participant eligibility is based on the date that a prescription is filled. In

order to determine eligibility for paper claims, GPP must establish the database so that GPP can access eligibility with respect to an 18-month period to take into account the potential lag time between the date the prescription is filled and the date a claim is filed.

4. Issue Prescription Cards to the Participants as directed by the Fund in a format satisfactory to the Fund;
5. Monitor the usage of prescription drugs filled through the Program to ensure that neither pharmacists nor Participants are abusing the Program, and provide periodic reports to the Fund.
6. Provide informational packets in a format approved by the Fund that explain the Program, including the three-tiered participant copayment, the amount of which is established from time to time by the Fund. GPP accepts the Fund's policy to not reimburse more than the generic cost of a drug (less applicable co-payment) when there is a generic equivalent drug, absent a written statement of medical necessity for a brand-name from the prescribing physician, and the other basic terms and conditions of the Program. *It being understood that a statement on the prescription of dispense as written would be considered a statement of medical necessity.*
7. Develop a system that will enable the Fund to access GPP's computer records of the Fund's eligibility files.
8. Maintain a special toll-free ("800") number for the exclusive use of Fund Participants.
9. Make good faith efforts to expand the network of pharmacies that participate in the program on an ongoing basis.
10. Send representatives to attend meetings at the Fund's request to report on the Program and industry developments and to respond to questions concerning the operation of the Program.
11. Make recommendations to the Fund with respect to possible improvements in the Program, including changes in the plan design.

b. Reimbursement

- i. The Fund shall reimburse GPP for the cost of prescriptions, as defined below, (including dispensing fees) filled by participating

pharmacies within ten (10) days of its receipt of properly itemized bill documenting the amounts paid by GPP, the date payments were made, the names and social security numbers of the individuals on behalf of whom payments were made and such other information as may reasonably be requested by the Fund.

- ii. GPP shall pay to participating pharmacies an amount equal to the Cost of prescriptions filled plus the dispensing fee (not to exceed Two Dollars and Twenty Five Cents (\$2.25) in Pennsylvania) for each prescription that is filled for an eligible Participant, less the amount of any co-payment received by the pharmacy by an eligible Participant. The dispensing fee payable to pharmacies outside of the Commonwealth of Pennsylvania shall be as low as GPP may in good faith negotiate and shall not exceed the maximum dispensing fee permitted by Medicaid. GPP shall provide to the Fund a list of the applicable dispensing fees for the states of New Jersey, New York and Delaware for such other states as the Fund may from time to time request. *The amount of the dispensing fee shall be the lesser of the dispensing fee negotiated between GPP and the pharmacy or the submitted dispensing fee of that pharmacy. In no case shall GPP keep a differential between the submitted dispensing fee and the dispensing fee billed to the Fund. (This means that if GPP pays a dispensing fee of \$1.99 for a prescription drug at a retail pharmacy, the Fund shall be responsible for a payment equaling a dispensing fee of \$1.99 for that prescription drug.)*

3. COST OF PRESCRIPTIONS TO THE FUND (the "Cost")

- a. It is understood by the parties that a major reason that the Fund has entered into this Agreement is to enable it to pay for prescription drugs at a price below the Average Wholesale Price, as that term is commonly understood in the pharmaceutical industry. Specifically, GPP represents that its charges to the Fund (the "Cost") for prescription drugs shall not exceed the following (reduced by the amount of the co-payment):

1. Brand-name drugs - effective rate of AWP less 16.6 percent.

2. Generic drugs - HCFA MAC or, for prescription drugs for which there does not exist a HCFA MAC price, the lowest reduction from AWP as GPP reasonably may negotiate. In determining the price for generic drugs, AWP shall mean the average wholesale cost of all generic drugs with the same chemical formula.

3. Cost of Prescriptions to the Fund

- a. *It is understood by the parties that a major reason that the Fund has entered into this Agreement is to enable it to pay for prescription drugs at*

*a price below the Average Wholesale Price ("AWP"). AWP shall be determined with reference to the price cited by FirstData Bank on the date that the drug was dispensed with respect to the appropriate NDC Code and the actual package size, not standard package size and other factors that the Trustees deem appropriate. Specifically, GPP represents that its charges to the Fund (the "Cost") for prescription drugs shall not exceed the following (reduced by the amount of the co-payment):*

*Brand-name drugs: The lesser of the negotiated AWP discount between the pharmacy or the amount actually paid by GPP for the prescription drug dispensed to the Fund's participant or beneficiary. (This means that if GPP pays AWP -23% for a prescription drug at a retail pharmacy, the Fund shall be responsible for a payment equaling AWP -23% for that prescription drug.)*

*Generic drugs: HCFA MAC, now referred to as FUL, or, for prescription drugs for which a FUL price does not exist, GPP shall negotiate the lowest reduction from AWP. This price is referred to as the GPP MAC price which in no event shall be more than three times the Wholesale Acquisition Cost (WAC) or Net Wholesale Unit Price*

*(WHN\_P) as defined by First Databank (The Hearst*

*Corporation, 111 Bayhill Drive, San Bruno, California 94066) on the date the drug was dispensed.*

*In no case shall GPP keep a differential between the cost of the prescription submitted and the cost of the prescription billed to the Fund.*

#### 4. ADMINISTRATIVE COSTS AND FEES

a. The Fund shall pay to GPP, as compensation for its services the following fees:

##### i. Prescription Card Usage Fees

Where the eligible Participant uses the Prescription Card at a participating pharmacy, the Fund shall pay to GPP the sum of Sixty cents (\$0.60) for each Prescription that is processed on behalf of an eligible Participant. Where an ineligible Participant presents a Prescription Card to a participating pharmacy, and GPP is charged for such attempted use, the Fund shall pay to GPP an amount not to exceed the lower of GPP's actual cost, or Twenty-Five cents (\$0.25).



ii. Paper Claims

Where an eligible Participant submits a claim for reimbursement to the Prescription Drug Administrator instead of using a Prescription Card, the Fund shall pay to GPP the sum of One Dollar and Fifty Cents (\$1.50) for each eligible claim processed. The Participant shall only be reimbursed by GPP the price of a generic equivalent of any drug (less the amount of applicable copayment) unless the Participant's physician states in writing that a brand name drug is medically necessary.

iii. Postage

The parties agree to bear the cost of postage for the various mailings GPP performs on behalf of the Fund as specifically set forth in this Agreement. By the term "postage" the parties mean the actual cost to GPP as charged by the outside carrier for 1) check payments to vendors; 2) direct reimbursements to Participants; 3) letters to physicians or other providers; and 4) general postage charged for matters directly necessary to the administration of the Fund's prescription plan; 5) *the exact cost of mailing/delivery of dispensed prescriptions to Participants*. The Fund will make payment for the postage by reimbursing GPP for those postage expenses actually incurred and properly documented.

iv. Charges for Prescription Cards

GPP will charge the Fund thirty cents (\$0.30) for each Prescription Card as requested directly by the Fund. GPP may charge the fund its actual cost incurred for postage or UPS charges for delivery of cards. GPP shall not provide additional cards to Participants except upon the request of the Fund.

v. Payment by Fund

In all cases, the Fund shall pay on a monthly basis administrative costs and fees by separate check within fifteen (15) days of receipt of an itemized bill from GPP. This bill shall include such information as may be requested by the Fund.

vi. No Other Charges

Except as specifically set forth in this Agreement, the Fund shall pay no other fees or charges to GPP.

5. SCOPE OF COVERAGE

- a. In general, the Program covers all prescription drugs which are "medically necessary" as determined under the Fund's Plan. Prescriptions for drugs the retail cost of which would exceed \$1,500 per prescription must be pre-certified under the Fund's Managed Care Program.



- b. The Fund will neither pay nor reimburse GPP for the processing of claims relating to drugs which require pre-certification unless the prescription is first approved under the Fund's managed care program.

6. BONDING AND INSURANCE

- a. GPP will obtain a fidelity bond in the amount of Five Hundred Thousand Dollars (\$500,000.00) naming the Fund as beneficiary in the event of the loss of Fund assets on account of theft, embezzlement, or dishonesty by an employee, owner, agent, or independent contractor of GPP.
- b. GPP will provide to the Fund a copy of liability insurance policy shall be acceptable to the Fund (covering both negligence and errors and omissions of GPP, its agents and employees) relating to their activities in connection with the Program in an amount not less than One Million Dollars (\$1,000,000.00). GPP also will provide to the Fund a copy of liability insurance which insurance policy shall be acceptable to the Fund (covering negligence, including malpractice, and errors and omissions of GPP, its agents and employees) in an amount not less than Five Million Dollars (\$5,000,000.00).

7. FORMULARY, REBATE, ALLOWANCES, ETC.

- a. Joel Grodman individually, and on behalf of GPP, represents that neither he, GPP, nor any person who is an agent or employee or owner of GPP, nor any person related to Joel Grodman or to any agent, employee or owner of GPP are receiving or will receive any money or any thing of value (whether in the form of cash, property, research grants, credits, services, advertising allowances or otherwise) from any pharmaceutical manufacturer, distributor, or other person or entity that engages directly or indirectly in the business of providing goods or services related to the pharmaceutical business that he, she, or it would not have received but for the Fund's participation in the Program. The foregoing representation shall not be construed to preclude that acceptance of manufacturer's allowances or rebates with respect to the purchase of any items covered under the Program, so long as one hundred percent of such amounts are passed through and credited to the Fund. To the extent any such amounts are received by any other entity and to the extent they relate to the Fund's participation in the Prescription Program, they shall be paid to the Fund. This representation is continuing in nature and shall survive this Agreement. In the event this Section 7 is breached, Joel Grodman and GPP shall pay to the Fund the fair market value of any amounts received by them or a related party, together with interest at a rate equal to the interest rate that the Internal Revenue Service charges on tax underpayments.

8. UTILIZATION REPORTS

- a. GPP shall provide to the Fund utilization reports on a *mutually agreed basis*. These reports shall set forth the total number of prescriptions

filled, the number of participants using the Program, the number of prescriptions filled at each of the participating pharmacies, the average cost of prescriptions filled, the average number of prescriptions filled per Participant, and such other information as may be requested by the Fund, including information concerning the mail order program. GPP agrees to provide to the Fund on a monthly basis claim utilization information on a magnetic tape in a form acceptable to the Fund. In addition, GPP will provide to the Fund specific information concerning prescriptions filled on behalf of any Participant and such other information as may be requested from time to time by the Fund.

9. **AUDIT RIGHT**

- a. GPP agrees to maintain adequate books and records concerning all financial and accounting activities of the Program. All such records, including all relevant background documentation, shall be open to inspection and audit upon reasonable notice by the Fund or an authorized representative thereof, including the Fund's counsel, or designated audit agent.
- b. On an annual basis, GPP shall provide to the Fund at the Fund's request, a Statement on Auditing Standards (SAS) No. 70, Type II audit report.

10. **PRIVACY**

- a. Fund and GPP agree to comply with the Administrative Simplification requirements of the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), as set forth in Title 45, Parts 160 and 164 of the Code of Federal Regulations (the "CFR").
- b. **Definitions.** Capitalized terms not otherwise defined in this Section 10 of the Agreement shall have the meanings given to them in Title 45, Parts 160 and 164 of the CFR and are incorporated herein by reference.
- c. **Use and Disclosure of Protected Health Information.** GPP shall use and/or disclose Protected Health Information ("PHI") only to the extent necessary to satisfy GPP's obligation under the Agreement.
- d. **Prohibition on Unauthorized Use or Disclosure of PHI.** GPP shall not use or disclose any PHI received from or on behalf of Fund, except as permitted or required by the Agreement, as required by law or as otherwise authorized in writing by Fund. GPP shall comply with: (a) Title 45, Part 164 of the CFR; (b) State laws, rules and regulations applicable to PHI not preempted pursuant to Title 45, Part 160, Subpart B of the CFR or the Employee Retirement Income Security Act of 1974 ("ERISA") as amended; and (c) Fund's health information privacy and security policies and procedures.
- e. **GPP's Operations.** GPP may use PHI it creates or receives for or from Fund only to the extent necessary for GPP's proper management and administration or to carry out GPP's legal responsibilities. GPP may disclose such PHI as necessary for GPP's proper management and

administration or to carry out GPP's legal responsibilities only if:

- i. The disclosure is required by law; or
  - ii. GPP obtains reasonable assurance, evidenced by written contract, from any person or organization to which GPP shall disclose such PHI that such person or organization shall;
    1. Hold such PHI in confidence and use or further disclose it to the person or organization or as required by law; and
    2. Notify GPP (who shall in turn promptly notify Fund) of any instance of which the person or organization becomes aware in which the confidentiality of such PHI was breached.
- f. **Data Aggregation Services.** GPP may use PHI to provide Data Aggregation Services related to Fund's Health Care Operations.
- g. **PHI Safeguards.** GPP shall develop, implement, maintain and use appropriate administrative, technical and physical safeguards to prevent the improper use or disclosure of any PHI received from or on behalf of Fund.
- h. **Electronic Health Information Security and Integrity.** GPP shall develop, implement, maintain and use appropriate administrative, technical and physical security measures in compliance with Section 1173 (d) of the Social Security Act, Title 42, Section 1320d-2(d) of the United States Code and Title 45, Part 142 of the CFR to preserve the integrity and confidentiality of all electronically maintained or transmitted Health Information received from or on behalf of Fund pertaining to an individual. GPP shall document and keep these security measures current.
- i. **Protection of Exchanged Information in Electronic Transactions.** If GPP conducts any Standard Transactions for or on behalf of Fund, GPP shall comply, and shall require any subcontractor or agent conducting such Standard Transaction to comply, with each applicable requirement of Title 45, Part 162 of the CFR. GPP shall not enter into or permit its subcontractors or agents to enter into any Trading Partner Agreement in connection with the conduct of Standard Transactions for or on behalf of Fund that: (a) changes the definition, Health Information condition or use of a Health Information element or segment in a Standard; (b) adds any Health Information elements or segments to the maximum defined Health Information set; (c) uses any code or Health Information elements that are either marked "not used" in the Standard's Implementation Specifications or are not in the Standard's Implementation Specification(s); or (d) changes the meaning or intent of the Standard's Implementation Specification(s).
- j. **Subcontractor and Agents.** GPP shall require each of its subcontractors or agents to whom GPP may provide PHI received from, or created or received by GPP on behalf of Fund to agree to written contractual provisions that impose at least the same obligations to protect such PHI as are imposed on GPP by the Agreement.
- k. **Access to PHI.** GPP shall provide access, at the request of Fund, to PHI

in a Designated Record Set, to Fund or, as directed by Fund, to an individual to meet the requirements under Title 45, Part 164, Subpart E, Section 164.524 of the CFR and applicable state law. GPP shall provide access in the time and manner set forth in Fund's health information privacy and security policies and procedures.

- l. **Amending PHI.** GPP shall make any amendment(s) to PHI in a Designated Record Set that Fund directs or agrees to pursuant to Title 45, Part 164, Subpart E, Section 164.526 of the CFR at the request of Fund or an Individual, and in the time and manner set forth in Fund's health information privacy and security policies and procedures.
- m. **Accounting of Disclosures of PHI.**
  - i. GPP shall document such disclosures of PHI and information related to such disclosures as would be required for Fund to respond to a request by an Individual for an accounting of disclosures of PHI in accordance with Title 45, Part 164, Subpart E, Section 164.528 of the CFR.
  - ii. GPP agrees to provide Fund or an individual, in the time and manner set forth in Fund's health information privacy and security policies and procedures, information collected in accordance with Section 11(a) above, to permit Fund to respond to a request by and individual for an accounting of disclosures of PHI in accordance with Title 45, Part 164, Subpart E, Section 164.528 of the CFR.
- n. **Access to Books and Records.** GPP shall make its internal practices, books and records relating to the use and disclosure of PHI received from or on behalf of Fund available to Fund and to DHHS or its designee for the purpose of determining Fund's compliance with the Privacy Rule.
- o. **Reporting.** GPP shall report to Fund any use or disclosure of PHI not authorized by the Agreement, by law, or in writing by Fund. GPP shall make the report to Fund's Privacy Official not less than 24 hours after GPP learns of such unauthorized use or disclosure; (b) identify the PHI used or disclosed; (c) identify who made the unauthorized use or received the unauthorized disclosure; (d) identify what GPP has done or shall do to mitigate any deleterious effect of the unauthorized use or disclosure; (e) identify what corrective action GPP has taken or shall take to prevent future similar unauthorized use or disclosure; and (f) provide such other information, including a written report, as reasonably requested by Fund's Privacy Official.
- p. **Mitigation.** GPP agrees to mitigate, to the extent practicable, any harmful effect that is known to GPP of a use or disclosure of PHI by GPP in violation of the requirements of the Agreement.
- q. **Termination for Cause.** Upon Fund's knowledge of a material breach by GPP, Fund shall:
  - i. Provide an opportunity for GPP to cure the breach or end the violation and terminate if GPP does not cure the breach or end the violation within the time specified by Fund.
  - ii. Immediately terminate the Agreement if GPP has breached a

material term of the Agreement and cure is not possible.

- iii. If neither termination nor cure is feasible, Fund shall report the violation to DHHS.

r. **Return or Destruction or Health Information.**

- i. Except as provided in Section 17(b) below, upon termination, cancellation, expiration or other conclusion of the Agreement, GPP shall return to Fund or destroy all PHI received from Fund, or created or received by GPP on behalf of Fund. This provision shall apply to PHI that is in the possession of subcontractors or agents of GPP. GPP shall retain no copies of the PHI.
- ii. In the event that GPP determines that returning or destroying the PHI is infeasible, GPP shall provide to Fund notification of the conditions that make return or destruction infeasible. Upon verification by Fund that the return or destruction of PHI is infeasible, GPP shall extend the protections of the Agreement to such PHI and limit further uses and disclosures of PHI to those purposes that make the return or destruction infeasible. Upon verification by Fund that the return or destruction of PHI is infeasible, GPP shall extend the protections of the Agreement to such PHI and limit further uses and disclosure of PHI to those purpose that make the return or destruction infeasible, for so long as GPP maintains such PHI.

- s. **Automatic Amendment.** Upon the effective date of any amendment to the regulations promulgated by HHS with respect to PHI, the Agreement shall automatically amend such that the obligations imposed on GPP as a GPP remain in compliance with such regulations.

11. **INVESTIGATIONS**

- a. GPP shall promptly notify the Fund of any dealings with federal or state investigators and provide sufficient information to the Fund so that the Fund may determine whether such investigations impact GPP's relationship with the Fund.

12. **INDEMNIFICATION**

- a. GPP agrees to indemnify the Fund and the Trustees for any damages, claims, or injuries (including legal fees and costs) arising out of their activities in connection with the Fund's Prescription Card and mail order programs.

13. **TERM**

- a. The term of this Agreement shall be from January 1, 2003 through December 31, 2004 *and shall be renewed biannually.*
- b. Notwithstanding the preceding, this Agreement may be terminated by either party at any time either for Cause or not for Cause under the following conditions. Either party may terminate this Agreement for any reason, or no reason, upon sixty (60) days' advance written notice. Any

party may terminate this Agreement for Cause upon two (2) days' advance written notice. For purposes of this Agreement, the terms Cause with respect to a party to this Agreement, shall mean (1) the insolvency or bankruptcy of the party, (ii) a criminal conviction of any individual or entity who is a principal owner or officer of a party, or (iii) any action or inaction by a party which likely could cause the Trustees of the Fund to breach their fiduciary duties to the Fund if the action (or inaction) were not remedied.

- c. This Agreement may be amended by the mutual written agreement of the parties.

14. **NOTICES**

- a. All notices required or contemplated by this Agreement shall be sent by Certified Mail, Return Receipt Requested, to each of the parties, addressed as follows:

**TO THE FUND:**

Teamsters Health & Welfare Fund of Philadelphia and Vicinity  
4th & Cherry Streets  
Philadelphia, PA 19106  
ATTENTION: William J. Einhorn, Administrator

**TO GPP:**

General Prescription Programs, Inc.  
61 Freeman Street  
5th Floor  
Newark, New Jersey 07105  
ATTENTION: Joel Grodman, Chairman of the Board

15. **RESOLUTION OF DISPUTES**

- a. In the event of any dispute arising between the Fund and GPP, the dispute shall be resolved by an impartial arbitrator who is a member of the Labor/ERISA panel, and who is selected pursuant to the Labor/ERISA Arbitration Rules of, the American Arbitration Association. Arbitration shall be held in the Philadelphia, Pennsylvania area, unless the parties mutually consent to another location. Each party shall pay one-half of the arbitration expenses, as well as its own costs. Notwithstanding the preceding, in the event the Fund is a defendant in a lawsuit brought by a Fund Participant or beneficiary, the Fund may sue GPP or any other party, who may be liable for damages to the Participant in the suit or who may be liable to the Fund under the indemnification provision of this Agreement.

16. **INTERPRETATION**

- a. This Agreement is made in the Commonwealth of Pennsylvania. Except

to the extent preempted by ERISA or other federal law, this Agreement shall be governed and interpreted according to the laws of the Commonwealth of Pennsylvania.

17. ASSIGNMENT

- a. Except as expressly provided herein, none of the parties herein, none of the parties hereto shall assign any of their rights or obligations under this Agreement to any other party without the prior written consent of the parties affected thereby.

IN WITNESS WHEREOF, the parties have caused this Agreement to be duly executed this \_\_\_\_ day of January 2003, by and through their authorized agents and representatives.

GENERAL PRESCRIPTION PROGRAMS, INC.

BY: \_\_\_\_\_  
JOEL GRODMAN, CHAIRMAN OF THE BOARD

TEAMSTERS HEALTH & WELFARE FUND  
OF PHILADELPHIA AND VICINITY

BY: \_\_\_\_\_  
WILLIAM J. EINHORN, ADMINISTRATOR